

# **TDxFLx<sup>®</sup> SYSTEM OPERATIONS MANUAL**

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As an operator of the TDxFLx<sup>®</sup> System, you are using state-of-the-art technology. This instrument is designed to function consistently and dependably.

The TDxFLx<sup>®</sup> System is backed by professionals who excel in engineering, training, and technical expertise. As part of our customer commitment, we teach you how to operate, maintain, and troubleshoot your instrument in our PACE\* accredited training program at our Dallas, Texas facility.

All information necessary to the operation of the TDxFLx<sup>®</sup> System is available in this manual.

**Section 1.0      System Description** details the use or function and provides characteristics, specifications, hazards, precautions, and limitations.

**Section 2.0      Installation** describes unpacking, installation procedures, and any special requirements.

**Section 3.0      Operation** provides principles of operation and detailed operating instructions and calibration procedures.

**Section 4.0      Diagnostic Checks** includes descriptions and detailed instructions for the diagnostic checks.

**Section 5.0      Maintenance** details service and maintenance procedures.

**Section 6.0      Troubleshooting** provides detailed troubleshooting procedures.

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March 1993

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Sincerely,



Nancy Grondhuis  
Manager, Laboratory  
Quality Assurance

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The revision status of the manual is indicated below. Be sure that the manual contains the latest revision number of all pages. Additional copies of this manual may be purchased (List No. 04A24-51).

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**Introduction**

This section provides details on:

- Theory of Operation
- Specifications
- Performance Characteristics
- System Components
- Keypad Functions
- Operational Precautions and Limitations

The TDxFLx<sup>®</sup> System is an automated system that performs a variety of laboratory tests:

- Therapeutic Drug Assays
- Hormones
- Clinical Chemistries
- Specific Proteins
- Toxicology/Abused Drugs

The TDxFLx<sup>®</sup> System is designed for use by a trained laboratory technician in hospitals and private laboratories.

The analyzer performs tests in three modes: random access, batch, and unit dose. The user can perform 1 to 8 different assays with up to 20 samples on a single carousel run.

**NOTE:** Toxicology/abused drug assays are tested in the batch mode of operation.

This manual describes the TDxFLx<sup>®</sup> System and its components, installation procedures, theory of operation, and operating procedures. The manual also provides a description of the various diagnostic checks, routine maintenance procedures, and a troubleshooting guide.





## Theory of Operation

This section provides a brief overview of the theory behind the operation of the TDxFLx<sup>®</sup> System. The system uses fluorescence polarization technology and competitive binding immunoassay methodology.

The system also uses radiative energy attenuation (REA<sup>®</sup>) technology to perform clinical chemistry assays, specific antisera and endpoint nephelometry technology to perform Turbo<sup>®</sup> Specific Protein assays (refer to the TDxFLx<sup>®</sup> & TDx<sup>®</sup> Turbo<sup>®</sup> Operation Supplement for further information). More in-depth information may be obtained from your Abbott Sales Representative or the [Customer Support Center](#) (CSC).

### Fluorescence Polarization Immunoassay

The TDxFLx<sup>®</sup> System uses fluorescence polarization immunoassay (FPIA) technology as detailed in the following paragraphs.

The tungsten halogen lamp in the system emits light of different wavelengths or colors with random spatial orientation. An interference filter, located in front of the light source, allows only blue light (481-489 nm) to pass through. The light is then passed through a liquid-crystal polarizer to produce plane polarized blue light.

The plane polarized blue light excites the tracer, or fluorophore, and raises it to an excited state. After excitation, the fluorophore returns to steady state by emitting green light (525-550 nm).

When the fluorophore is bound to a large antibody molecule, it does not rotate freely, and the emitted green light will be in the same plane as the blue excitation light and polarization is retained. Conversely, when the fluorophore is free to rotate, the emitted green light will be in a different plane than the blue excitation light and polarization will be lost.

Therefore, because of the rotational properties of molecules in solution, the degree of polarization is directly proportional to the size of the molecule. That is, polarization increases as molecular size increases.

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### **Competitive Binding Immunoassay**

The TDxFLx<sup>®</sup> System uses a competitive binding immunoassay methodology to allow tracer-labeled antigen and patient antigen to compete for binding sites on the antibody molecules. The components in this competitive binding reaction are the antibody, the patient antigen, and the antigen labeled with fluorescein (tracer-antigen complex). When competitive binding occurs, the more tracer-antigen complex that binds to the antibody molecule, the less tracer-antigen complex that remains in solution.

If a patient sample contains a low concentration of antigen, after the competitive binding reaction reaches steady-state, there is a high concentration of bound tracer in the reaction mixture and polarization is high. Conversely, if a patient sample contains a high concentration of antigen, after the competitive binding reaction reaches steady-state, there is a low concentration of bound tracer in the reaction mixture and polarization is low. The precise relationship between polarization and concentration of the unlabeled drug or hormone in the sample is established by measuring the polarization values of calibrators with known concentrations of the drug or hormone.

Using the polarization values generated for each sample in the assay, concentrations of drugs or hormones in unknown samples are calculated using the stored calibration curve, and the results are printed out in reportable units.

### **Radiative Energy Attenuation Technology**

Radiative Energy Attenuation (REA<sup>®</sup>) technology applies the fundamental principles of Beer's Law. These principles are used in order to perform analysis of clinical chemistries on the TDxFLx<sup>®</sup> System.

The measured fluorescence intensity of a solution containing a fluorophore is proportional to the absorbance of the solution. If the solution has an absorbance greater than zero, an attenuation of the fluorescence intensity will be observed. The degree of attenuation will be directly proportional to the absorbance of the solution.

Radiative energy attenuation can be used to measure the concentration of specific analytes. When a reagent-analyte reaction generates a chromogen in the presence of a fluorophore, an attenuation of the fluorescence intensity is observed when the chromogen absorbs either the blue fluorophore-excitation or green fluorophore-emission light. If the chromogen absorbs the excitation light only, primary attenuation will be observed. If the chromogen absorbs the emission radiation only, secondary attenuation will be observed. If the chromogen absorbs both the excitation and emission radiation, the total attenuation will be proportional to the sum of the absorbances of the solution at each wavelength. Final fluorescence intensity will be inversely proportional to the amount of chromogen in the solution.

Through the use of calibrators, fluorescent intensities can be compared, and the analyte concentration in a patient's sample can be calculated. In a sample containing a low concentration of analyte, a small amount of chromogen will be produced, a small amount of light will be absorbed, the attenuation will be small, and the fluorescence intensity will be large. In a sample containing a high concentration of analyte, a large amount of chromogen will be produced, a large amount of light will be absorbed, the attenuation will be large and the fluorescence intensity will be small.

The fluorescence intensity is measured before and after the generation of the chromogen and the percent of light that was not attenuated is calculated. Concentrations of analyte are determined from a previously stored calibration curve and printed in reportable units.

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13. Khalil OS, Routh WS, Lingenfelter K, Carr DB, Ladouceur P. Automated in-line ratio-correcting filter fluorometer. *Clin Chem* 1981; 27: 1586-91.
14. Shaffar MR, Stroupe SD. A general method for performing routine clinical chemistry on the Abbott TDx analyzer. *Clin Chem* 1983; 129, 1251. Abstract.

**Table 1-1 TDxFLx<sup>®</sup> Analyzer Specifications**
**General Characteristics**

Capacity	Sample Carousel: 1 to 20 samples
Sample Volume	Reagent Carousel: 1 to 8 TDxFLx <sup>®</sup> wedge reagent packs
Carryover	50 to 500 µL
	< 1.5% at concentrations ≥ the highest calibrator, unless otherwise specified
Intensity/Stability	Better than 0.1% over the duration of an assay
Polarization Range	0 to 500 mP

**Physical Characteristics**

Size	24" D × 28" W × 15" H (60 cm D × 70 cm W × 37.5 cm H)
Weight	107 lbs (49 kg) maximum

**Electrical Characteristics**

Voltage	100 (+10%, –5%) 120, 220, or 240 VAC (+10%, –15%)
Frequency	50 or 60 Hz
Power Requirements	600 V-A
Fusing	100/120 VAC: 6.25 Amps T (SLO-BLO), 250 VAC 220/240 VAC: 3 Amps T (SLO-BLO), 250 VAC
Power Connection	3-prong grounded outlet (U.S.)
IEC Equipment Classification	Class I, Type B, Ordinary Equipment, Continuous Operation

**Environmental Requirements**

Room Temperature	15° to 30°C (59° to 86°F)
Humidity	15% to 85% humidity
Location	Flat, level surface No direct sunlight or drafts Removed from sources of direct heat and moisture Ventilation space at least 6" on top, sides, and back

**Optical Characteristics**

Light Source	Tungsten halogen lamp, 50 watts, 8 volts
Detector	Photomultiplier tube
Excitation Peak	485 nm
Excitation Bandwidth	8 nm
Emission Band	525 to 550 nm

**RS232 Serial Port**

The TDxFLx<sup>®</sup> System has a 25-pin connector for an RS232 serial communications port. The port has two modes of operation:

1. Echo Mode - All printed run information is also sent to the port.
2. Spooler Mode - Printed information is held in the system until called for by the host system.

For further information, contact the **Customer Support Center** for the system interface specification.

**Barcode Scanner**

Maximum Code Length: 2.75" (70 mm)

Narrow Bar Width: .004" (.08 mm) minimum

Barcode Symbology: Codabar, Code 3 of 9, Code 128 and Interleaved 2 of 5

Print Contrast Ratio: 25% minimum

Performance Characteristics

The following performance characteristics apply to the TDxFLx<sup>®</sup> System and to its test components.

Throughput

Random Access Pipetting Sequence (minutes)

	<u>Mode 1</u>	<u>Mode 17</u>
One Sample:	9 min.	9 min.
Full Carousel:	22 min.	22 min.

Batch Pipetting Sequence (minutes)

	<u>Mode 1*</u>	<u>Mode 2</u>	<u>Mode 3</u>	<u>Mode 4</u>	<u>Mode 5</u>	<u>Mode 6</u>
One Sample:	6 min.	16 min.	All Dilutes 13 min.	14 min.	9 min.	9 min.
Full Carousel:	13 min.	24 min.	20 min.	24 min.	18 min.	18 min.
	<u>Mode 7</u>	<u>Mode 8</u>	<u>Mode 9</u>	<u>Mode 10</u>	<u>Mode 11</u>	<u>Mode 12</u>
One Sample:	22 min.	12 min.	16 min.	3 min.	16 min.	9 min.
Full Carousel:	30 min.	18 min.	25 min.	25 min.	25 min.	19 min.
	<u>Mode 14</u>	<u>Mode 17</u>	<u>Mode 18</u>	<u>Mode 19</u>	<u>Mode 21</u>	<u>Mode 23</u>
One Sample:	9 min.	9 min.	16 min.	13 min.	14 min.	19 min.
Full Carousel:	18 min.	15 min.	24 min.	19 min.	19 min.	30 min.
	<u>Mode 24</u>	<u>Mode 25</u>	<u>Mode 26</u>	<u>Mode 27</u>	<u>Mode 28</u>	<u>Mode 30</u>
One Sample:	16 min.	16 min.	16 min.	16 min.	15 min.	13 min.
Full Carousel:	24 min.	24 min.	24 min.	22 min.	23 min.	19 min.
	<u>Mode 31</u>	<u>Mode 33</u>	<u>Mode 37</u>	<u>Mode 40</u>	<u>Mode 42</u>	<u>Mode 43</u>
One Sample:	27 min.	16 min.	12 min.	All Dilutes 13 min.	All Dilutes 16 min.	14 min.
Full Carousel:	30 min.	24 min.	20 min.	22 min.	24 min.	21 min.

\*Since most TDx<sup>®</sup>/TDxFLx<sup>®</sup> System assays are run in the Mode 1 pipetting sequence, it is described on the following page. For more details on sequences of pipetting modes, contact the **Customer Support Center**.



Unit Dose Pipetting Sequence (minutes)

	<u>Mode 1</u>	<u>Mode 4</u>	<u>Mode 17</u>	<u>Mode 22*</u>	<u>Mode 23</u>
One Sample:	8 min.	16 min.	8 min.	23 min.	26 min.
Full Carousel:	19 min.	25 min.	19 min.	29 min.	35 min.

\*Mode 22 is reserved for Turbo® (Specific Protein) assays.

Mode 1 Pipetting

After the instrument passes all the initialization checks, the pipetting sequence begins. In Mode 1, sample is aspirated from the sample well and dispensed with X SYSTEMS® Dilution Buffer into the predilution well of the sample cartridge. This dilution of sample provides greater accuracy of pipetting the sample volume, because a larger volume of diluted sample will be pipetted into the cuvette for the assay. One-half the final volume of the diluted sample, the “P” reagent, and X SYSTEMS® Dilution Buffer are dispensed into the cuvette to give one-half the final reaction volume. Background intensity readings are taken on this mixture. The second half of the diluted sample volume is added to the cuvette along with the “T” reagent, “S” reagent, and X SYSTEMS® Dilution Buffer to give the final reaction volume. The cuvette is incubated until the reaction reaches equilibrium, then final intensity readings are taken.

Reagents, Calibrators,  
Controls, and  
Pretreatment  
Reagents

Shipped ready-to-use  
Stable calibration  
X SYSTEMS<sup>®</sup> products expire the last day of the month printed on the label, unless otherwise specified

Precision Dispenser

Spring-loaded plunger  
Repetitive pipettings  
Chemically inert disposable tip

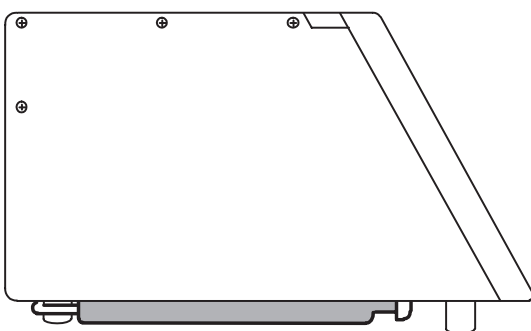
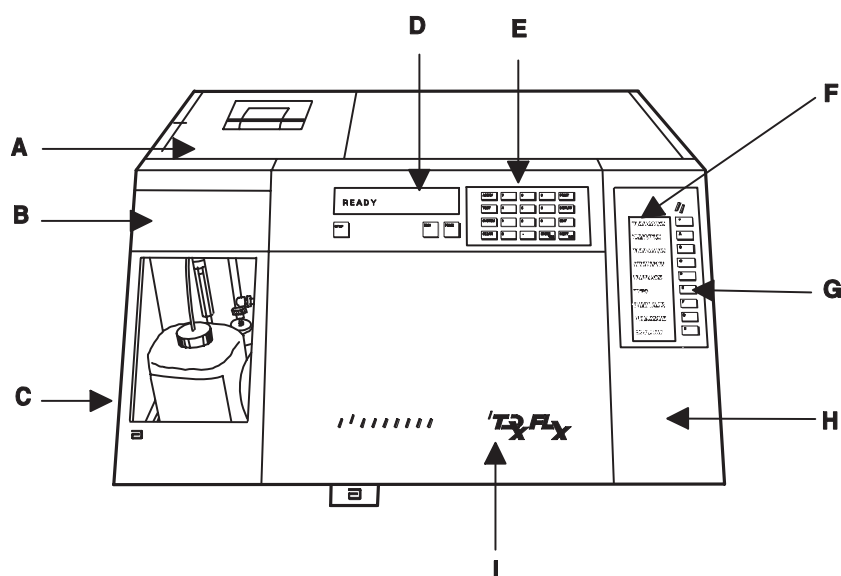
TDxFLx<sup>®</sup> Analyzer

Automatically reads sample blank when required by the specific assay mode

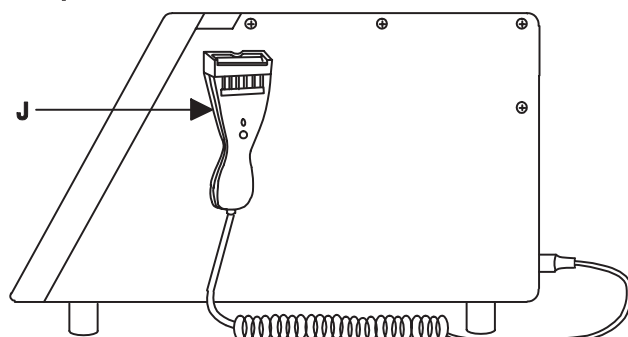
## TDxFLx<sup>®</sup> Analyzer (No. 04A24-XX)

The external features shown are:

- A. Printer Access Door
- B. Buffer Access Door
- C. Waste Container (Under Left Side)
- D. System Status Display
- E. Control Keypad
- F. Reagent Display
- G. Reagent Keypad
- H. Reagent Display Panel
- I. Carousel Access Door
- J. Barcode Scanner (Mounted on Side Panel)



LEFT SIDE



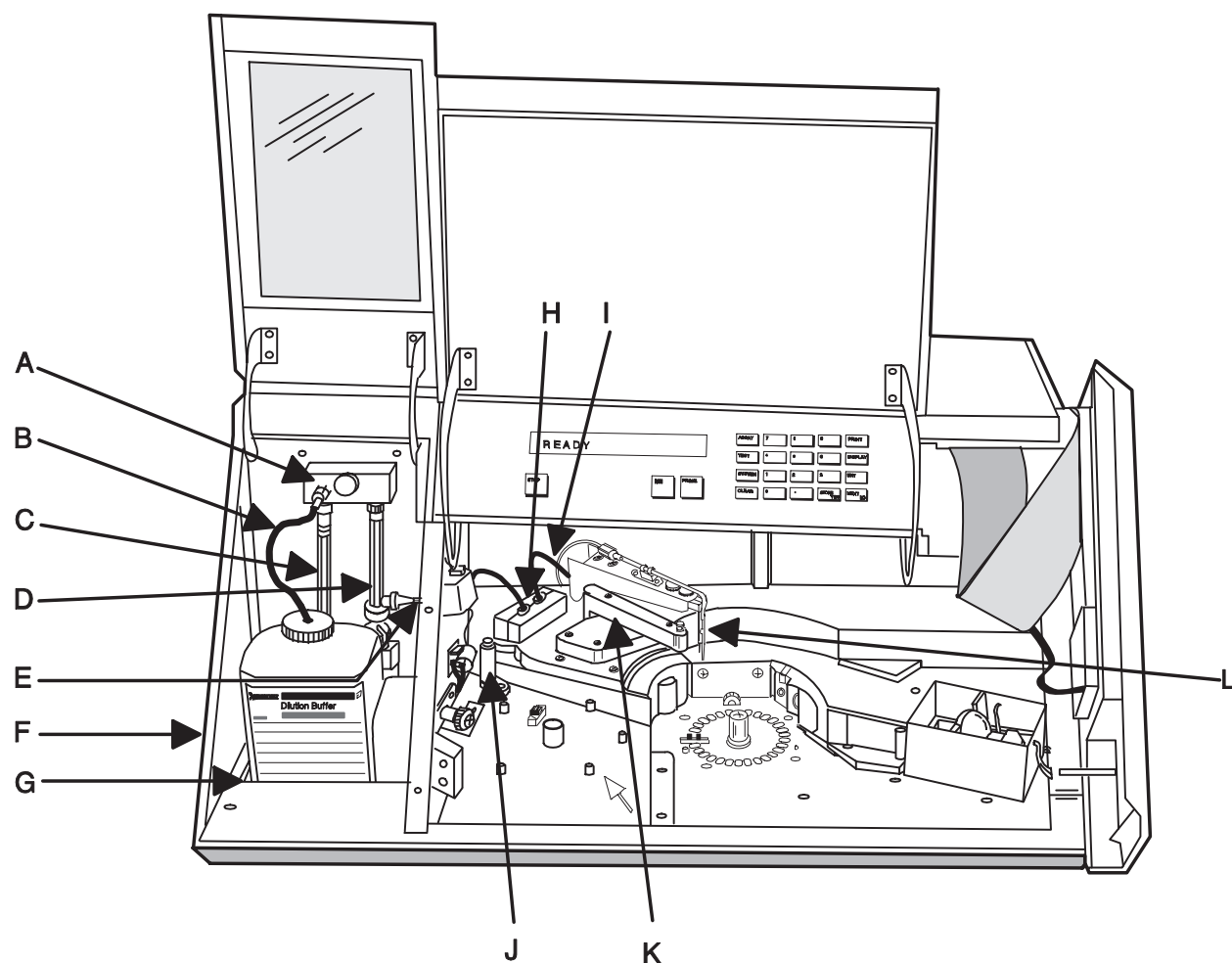
RIGHT SIDE

The internal components of the TDxFLx<sup>®</sup> System consist of the dispenser assembly, the optics assembly, and the sensors.

### Dispenser Assembly

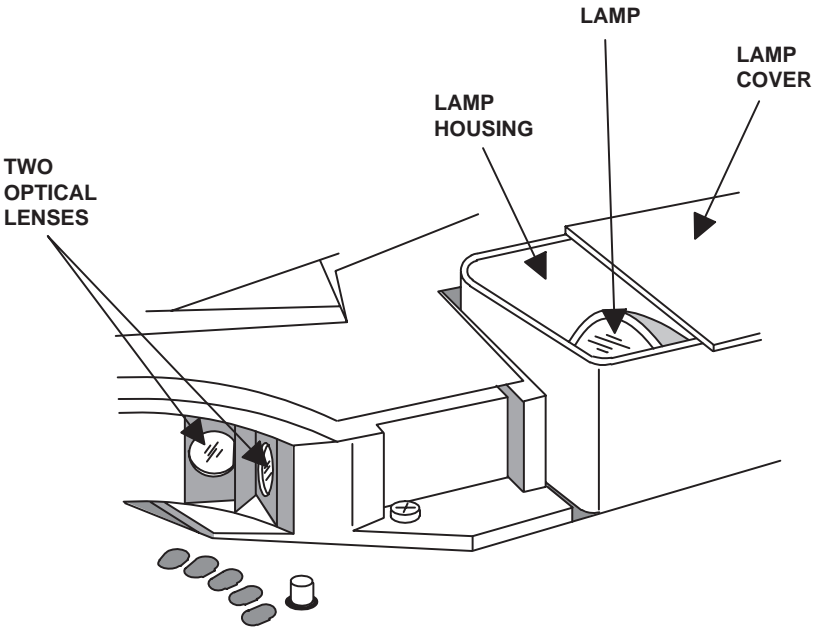
The features of the dispenser assembly are:

- A. Valve Block
- B. Inlet Tubing
- C. Diluent Syringe
- D. Sample Syringe
- E. Interconnect Tubing
- F. Waste Container (underneath baseplate)
- G. Buffer Platform
- H. Liquid Heater Block
- I. Probe Connector Tubing
- J. Waste/ Wash Station
- K. Boom Arm
- L. Probe



Optics Assembly

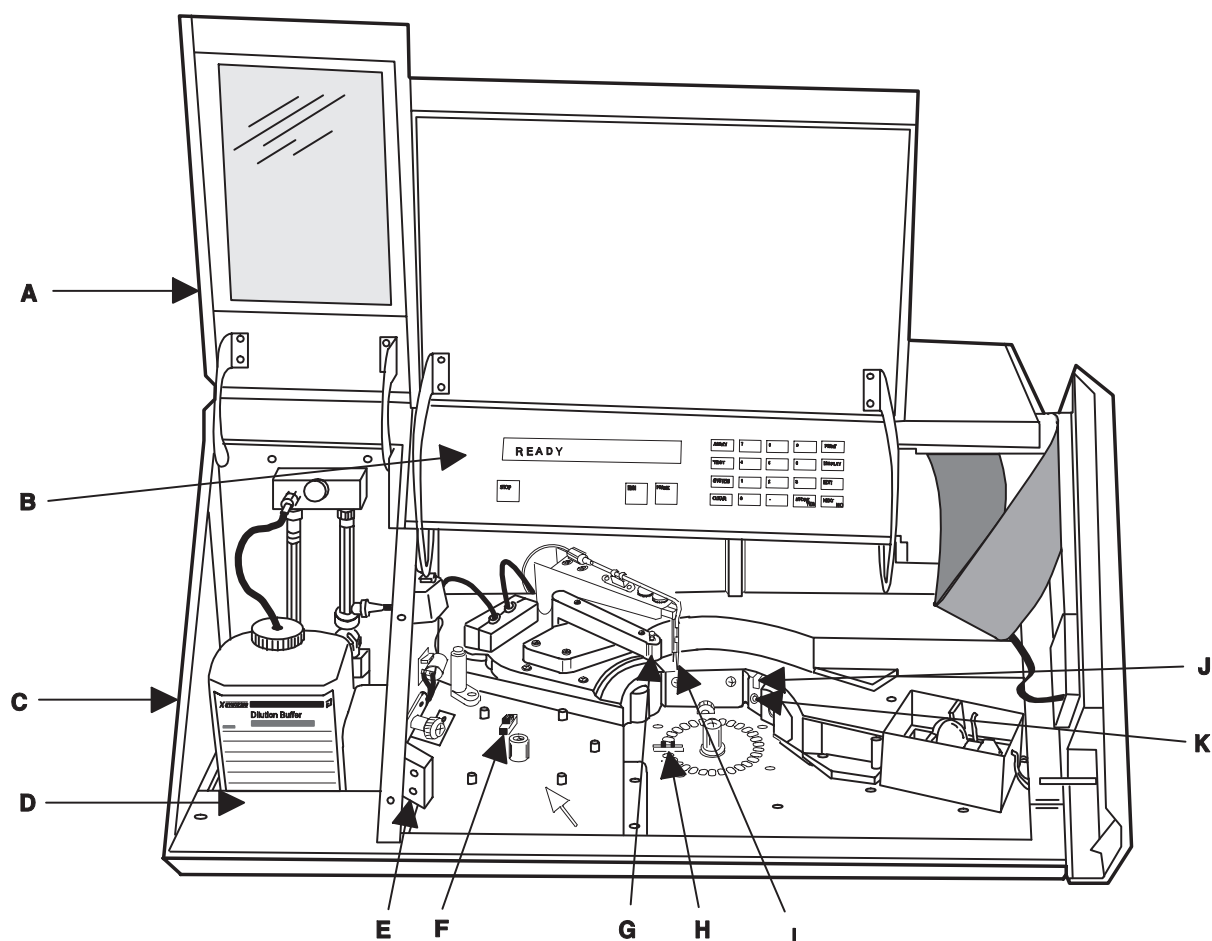
The optics assembly features:



### Sensors

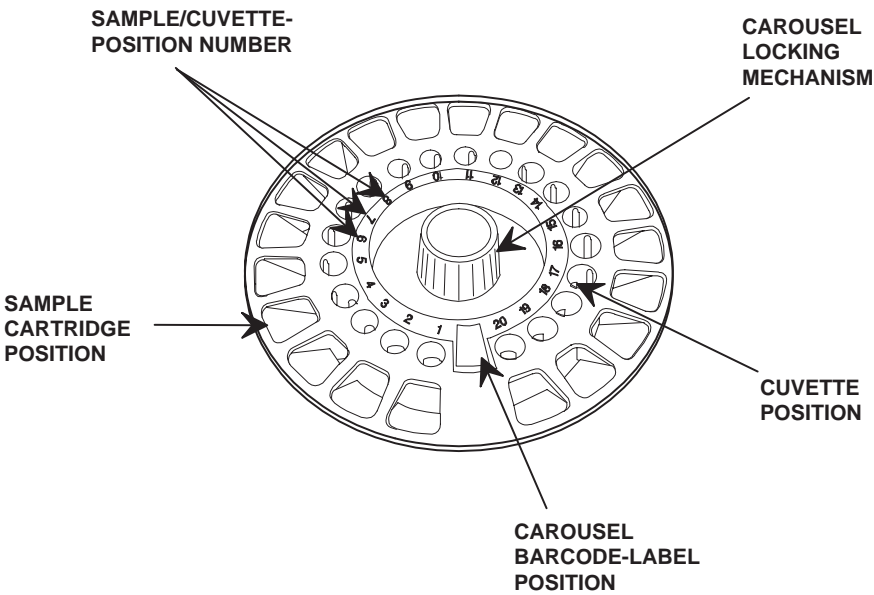
The sensors in the TDxFLx<sup>®</sup> System are:

- A. Paper Out Sensor (on printer assembly)
- B. Door Sensor (behind display panel)
- C. Waste Container Sensor (behind pump)
- D. Buffer Sensor (underneath platform)
- E. Reagent Carousel Barcode Reader
- F. Reagent Carousel Home Sensor
- G. Boom-Arm Barcode Reader
- H. Sample Carousel Home Sensor
- I. Liquid-Level Sensors
- J. Cuvette/Carousel-Locked Sensor
- K. Thermal Detector



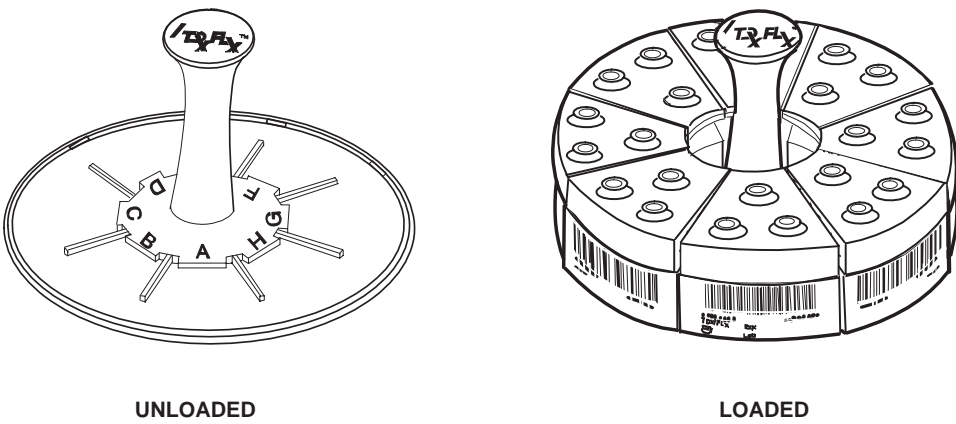
**X SYSTEMS® Carousel**  
(No. 9518-11)

This carousel is used in the random-access and batch modes for assay and calibration runs. The barcode label identifies the carousel's function. Carousels and barcode labels are shipped with the instrument. The carousel accommodates up to 20 samples. This carousel contains:



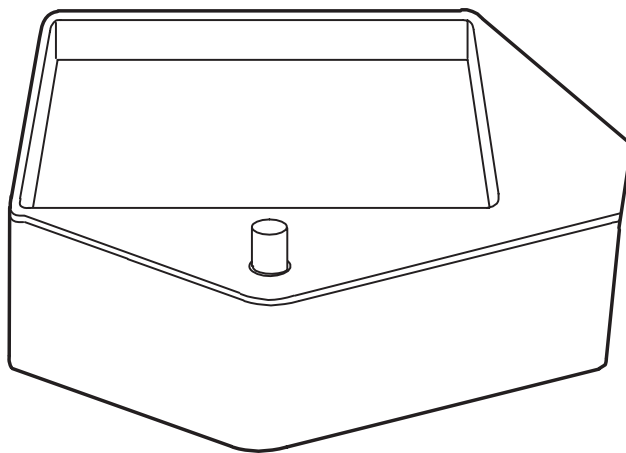
**TDxFLx® Reagent Carousel**  
(No. 04A24-10)

This reagent carousel holds reagents for random-access testing. The carousel holds eight of the wedge-shaped reagent packs.



**TDxFLx<sup>®</sup> Batch-Pack  
Adapter**  
(No. 04A24-11)

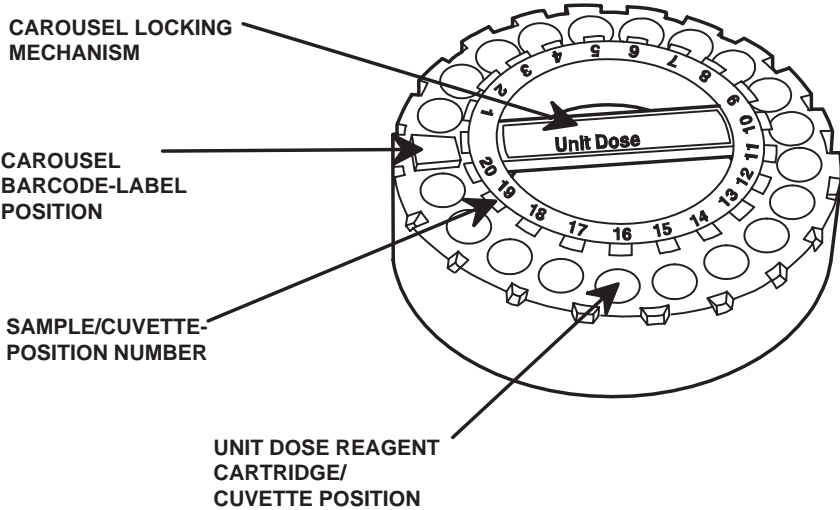
The TDxFLx<sup>®</sup> Batch-Pack Adapter allows the operator to run in batch mode on the TDxFLx<sup>®</sup> analyzer. The adapter is a platform that holds the **batch reagent pack**.





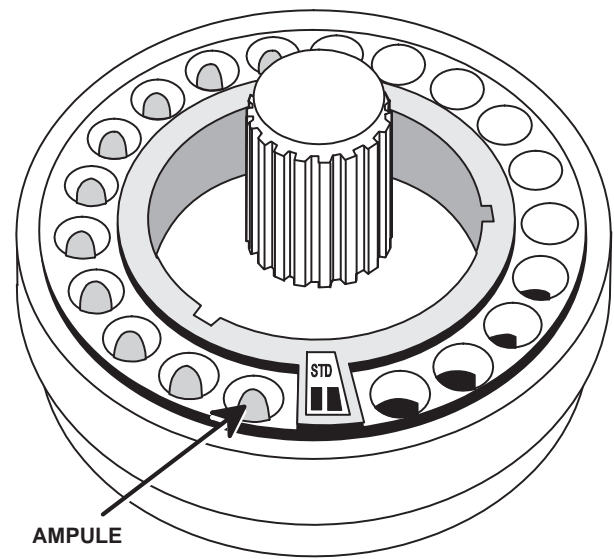
**Unit Dose Reagent  
Carousel**  
(No. 9520-50)

The unit dose reagent carousel enables the TDxFLx<sup>®</sup> analyzer to perform unit dose testing. The unit dose reagent carousel accommodates up to 20 individual cartridges. The features of the carousel are:



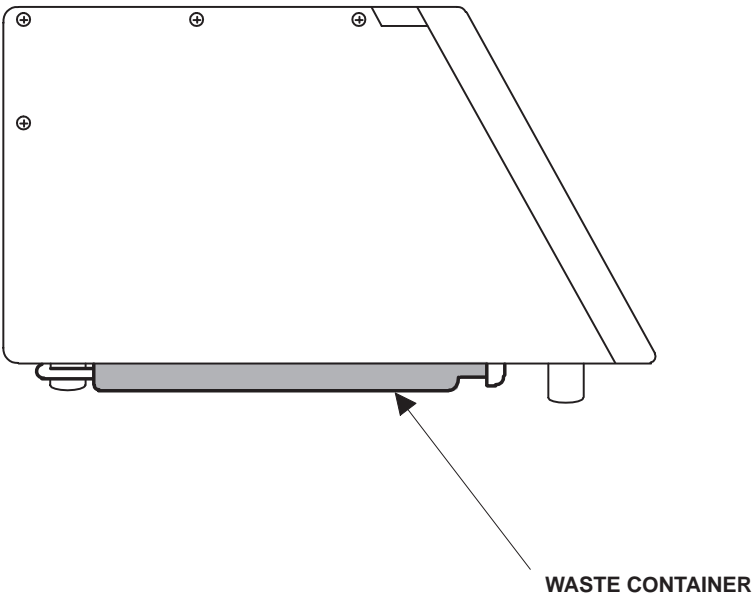
**X SYSTEMS®**  
**Fluorometric**  
**Standards Function**  
**Test Set Carousel**  
(No. 9520-31)

X SYSTEMS® Fluorometric Standards Function Test Set Carousel contains 10 sealed ampules of fluorescent dye (Rhodamine 110) in solution.



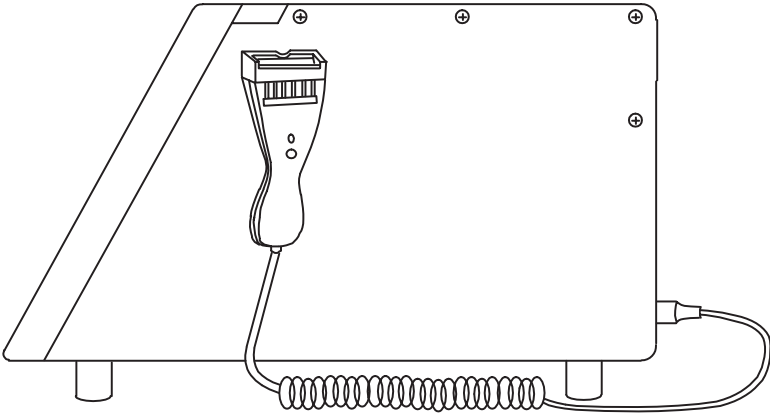
**TDxFLx<sup>®</sup> Waste Container**  
(No. 04A24-12)

The TDxFLx<sup>®</sup> Waste Container is a high density polyethylene waste receptacle that nests under the left side of the instrument.



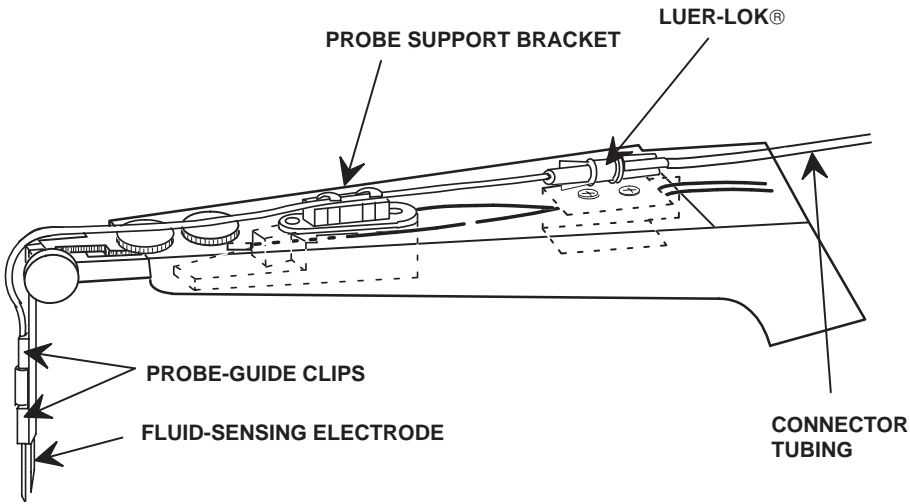
**TDxFLx<sup>®</sup> Barcode Scanner**  
(No. 04A24-15)

The hand-held barcode scanner reads Code 3 of 9, Code 128, Interleaved 2 of 5 and Codabar symbologies. The scanner accepts alpha-numeric characters for Patient ID and Operator ID even though the keypad does not have alpha keys. The holder permits mounting on either side of the instrument in a variety of positions.



**X SYSTEMS® Stainless Steel Probe**  
(No. 9967-02)

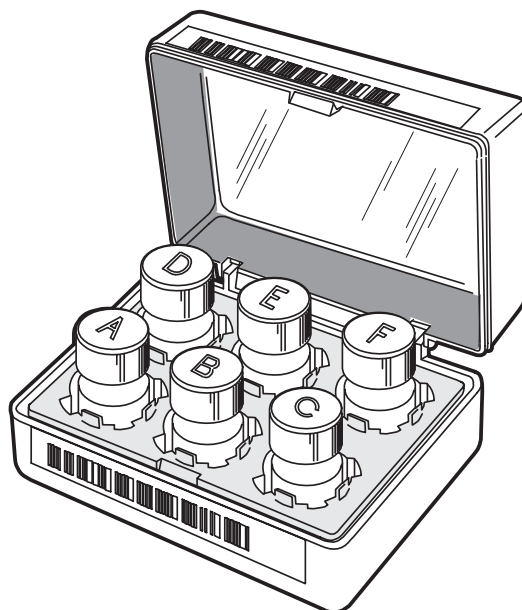
TDxFLx® System requires the TEFLON® coated, stainless steel probe for random-access, batch, and unit dose modes of operation. The stainless steel probe features sturdy construction, fluid-sensing electrodes, and LUER-LOK® fitting for disconnect/reconnect.



TEFLON is a registered trademark of E.I. duPont de Nemours & Co., Inc.  
LUER-LOK is a registered trademark of Becton Dickinson & Co.

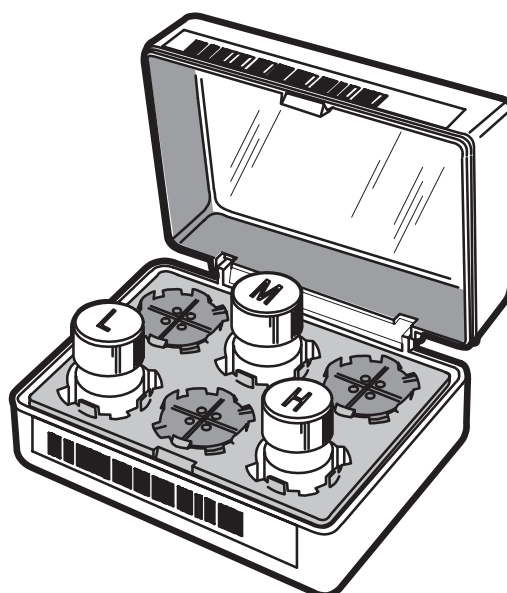
## X SYSTEMS<sup>®</sup> Calibrators

The calibrators consist of six vials, A through F. For further details, refer to the assays manual.



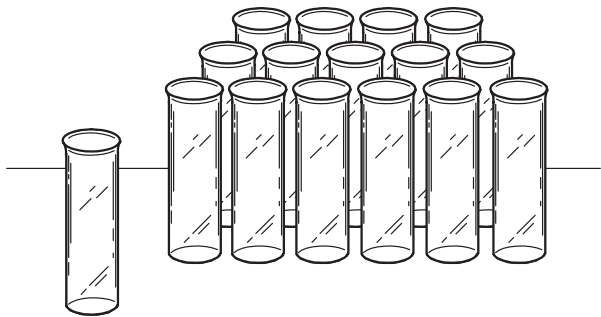
## X SYSTEMS<sup>®</sup> Controls

The controls for most assays consist of three vials, Low, Medium, and High. Controls for some assays contain vial quantities other than three. For further details, refer to the appropriate assay section in the assays manual.



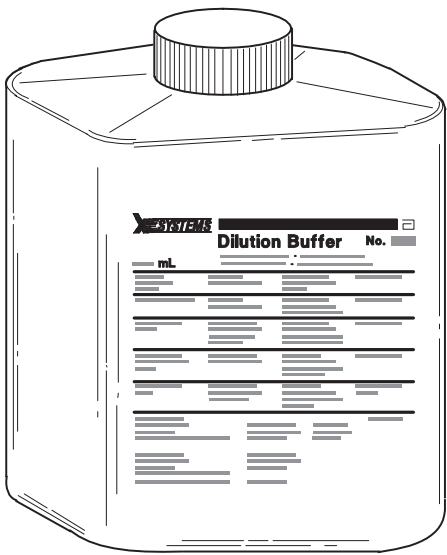
**X SYSTEMS® Cuvettes**  
(No. 9518-06)

Glass cuvettes are available in quantities of 100.



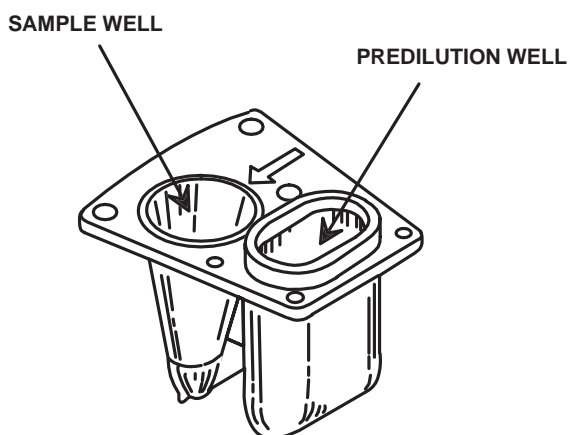
**X SYSTEMS® Dilution Buffer**  
(No. 9519-02)  
or  
(No. 9519-05)

The dilution buffer is a 0.1M phosphate buffer containing 0.1% sodium azide as a preservative.



**X SYSTEMS<sup>®</sup> Cartridges**  
(No. 9518-05)

These sample cartridges are used for random-access and batch testing. Cartridges are packaged in quantities of 100. The sample cartridges have a sample well and a predilution well.

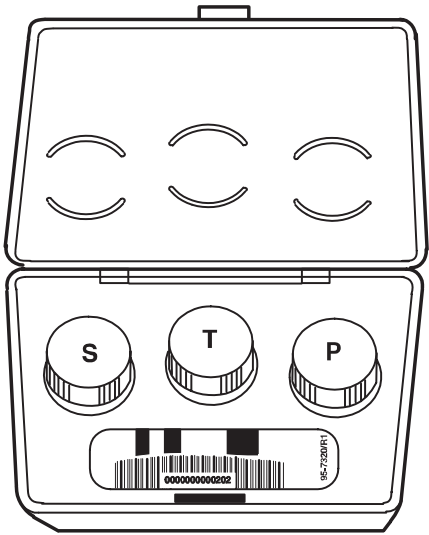


Reagents

The TDx<sup>®</sup>/TDxFLx<sup>®</sup> 3- and 4-pot reagent packs are used with the **batch-pack adapter** to run TDxFLx<sup>®</sup> in batch mode. Refer to the assays manual for details on the contents of each reagent vial/well.

The 3-pot reagent pack consists of:

- “S” Vial
- “T” Vial
- “P” Vial

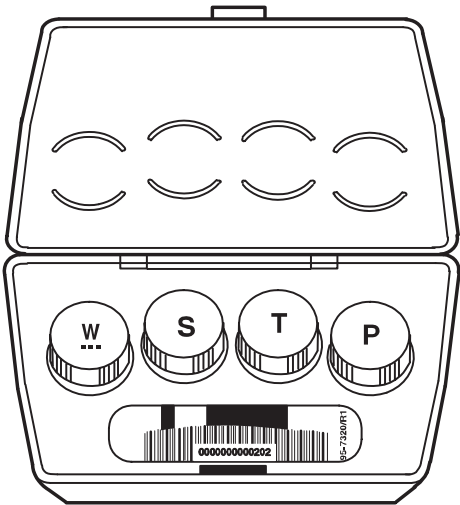


3-POT REAGENT PACK

**NOTE:** Vials in the T-Uptake reagent pack are in the order P-T-P.

The 4-pot reagent pack consists of:

- “W” Vial
- “S” Vial
- “T” Vial
- “P” Vial



4-POT REAGENT PACK

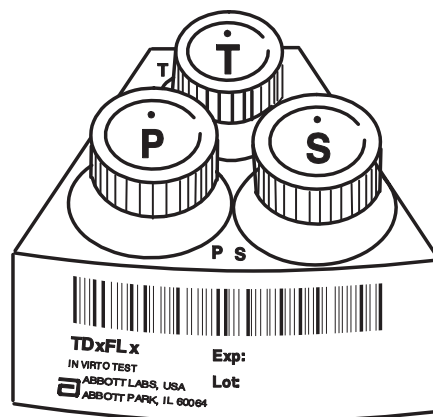


The TDxFLx<sup>®</sup> Reagent Pack is a wedge-shaped, 3-pot pack that is used for the random-access mode. The TDxFLx<sup>®</sup> System reagent carousel holds eight reagent packs. Each pack snaps onto the carousel and contains:

“S” Vial

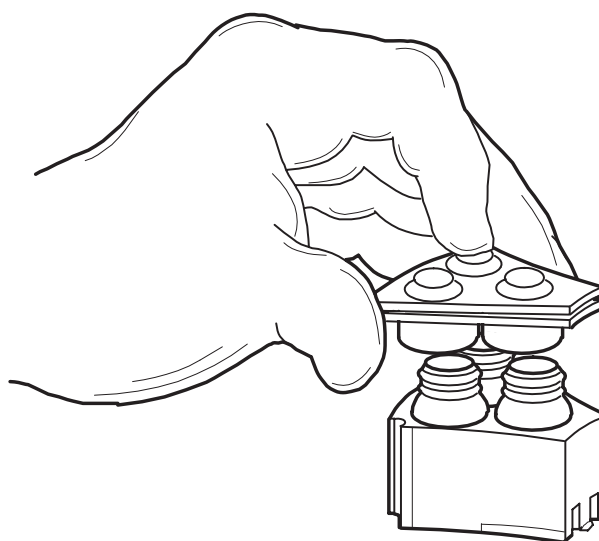
“T” Vial

“P” Vial



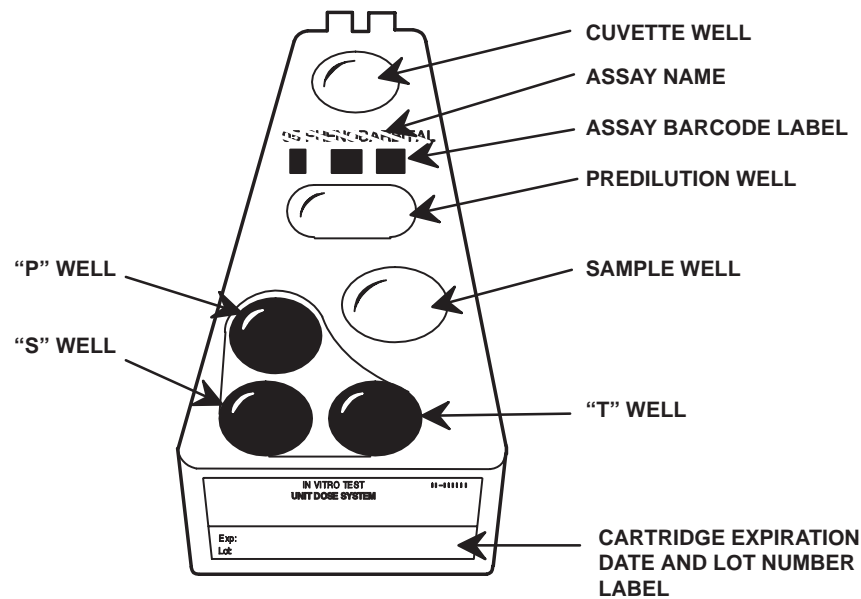
TDxFLx<sup>®</sup> REAGENT PACK

The TDxFLx<sup>®</sup> wedge reagent pack has snap caps that are used for storing the reagent packs after the initial use. The caps snap into place sealing all three pots simultaneously as shown below.



TDxFLx<sup>®</sup> REAGENT PACK WITH SNAP CAPS

The features of the unit dose reagent cartridge are:

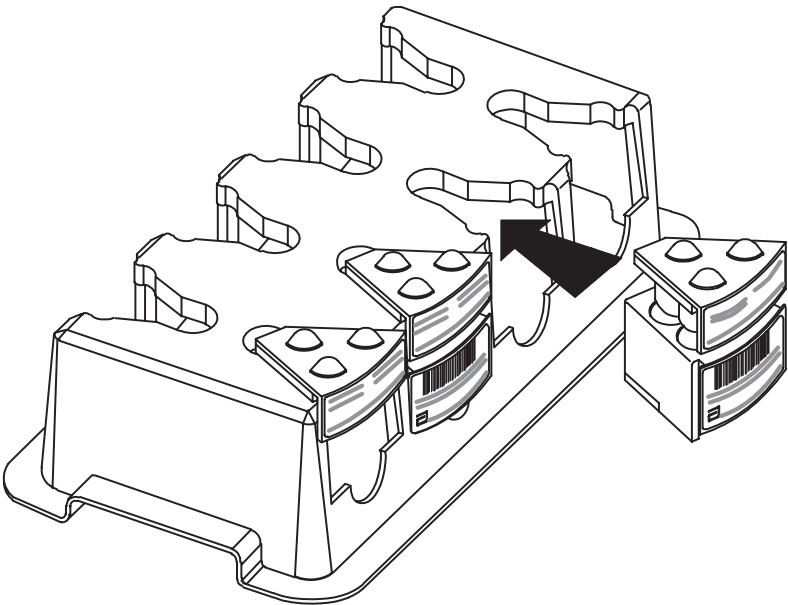


UNIT DOSE REAGENT CARTRIDGE

**TDxFLx® Snap Cap Organizer**  
(No. 4A24-35)

The snap cap organizer is provided as an aid to organize and store wedge reagents. The organizer can hold up to eight snap caps while the wedge reagent packs are in use during a random access run. Wedge reagent packs sealed with snap caps can be stored on the organizer before and after a random access run.


Place items on the organizer as shown below:

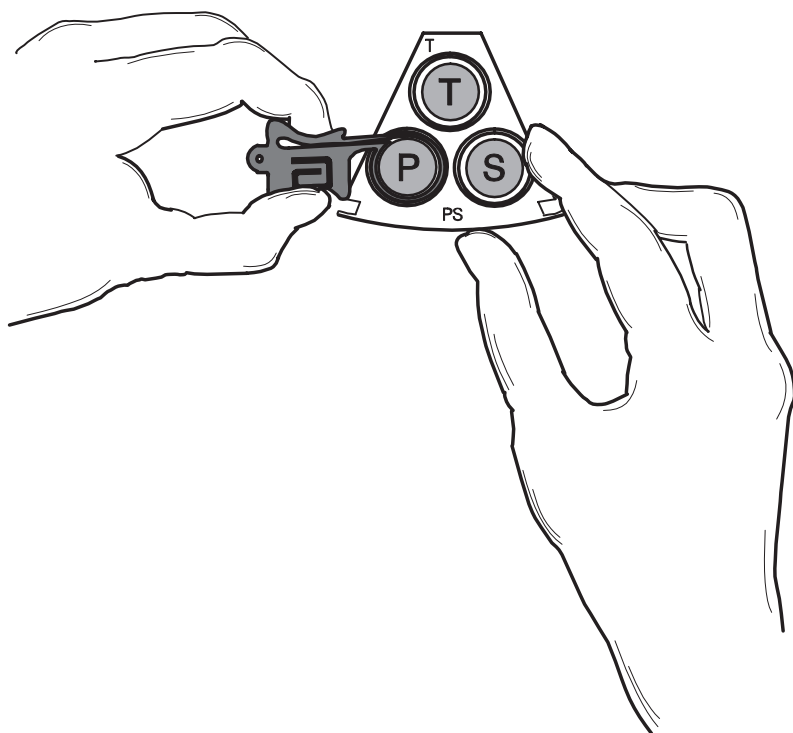


## X SYSTEMS® Wrench (No. 9684-25)


The X SYSTEMS® wrench is provided to assist with loosening or tightening reagent vial lids.

To loosen a vial lid with the wrench, perform the following steps:

1. Hold the wrench so that the Abbott Laboratories logo (  ) is face up.
2. Place the ring portion of the wrench around the vial lid.
3. Squeeze the opposite end of the wrench between your thumb and index finger.
4. Turn the wrench in a counterclockwise direction until the lid loosens.



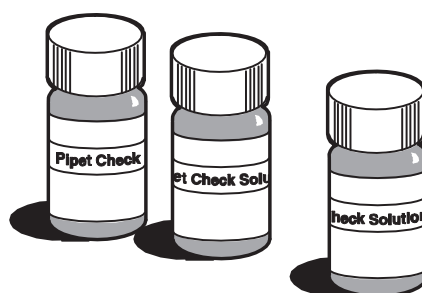
To tighten a vial lid using the wrench, perform the following steps:

1. Hold the wrench so that the Abbott Laboratories logo (  ) is face down.
2. Place the ring portion of the wrench around the vial lid.
3. Squeeze the opposite end of the wrench between your thumb and index finger.
4. Turn the wrench in a clockwise direction until the vial lid is tightened.

## Calibration Products

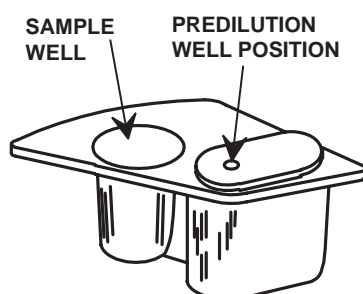
The TDxFLx<sup>®</sup> System requires the following products for instrument specification checks and calibration procedures.

### 1. X SYSTEMS<sup>®</sup> Pipet Check Solution (No. 9531-02)

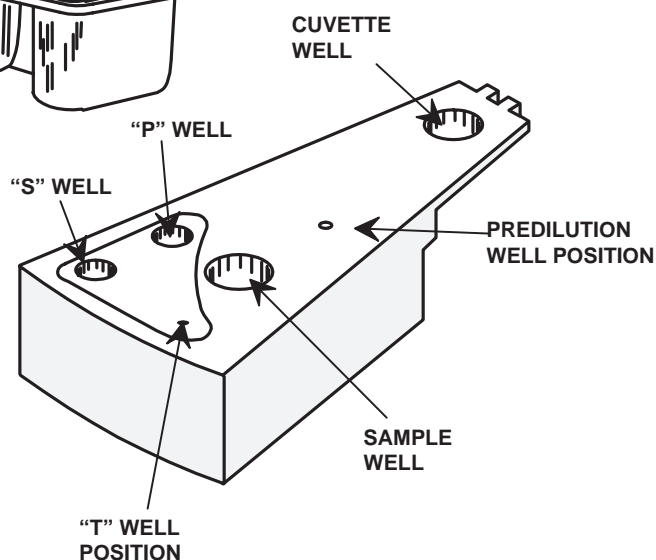


### 2. Probe Positioning Cartridges

Batch and  
Random Access  
(No. 9520-28)



Unit Dose  
(No. 9520-41)

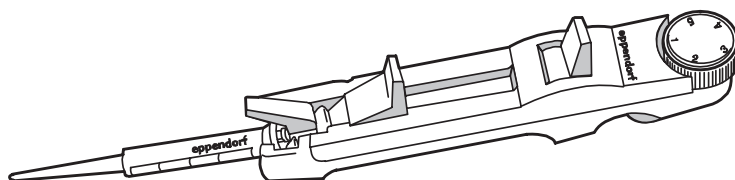


**Pretreatment Products**

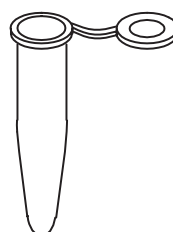
The TDxFLx<sup>®</sup> System requires the following additional products for assays requiring pretreatment steps:

**NOTE:** Any additional materials required for individual assays are described in the appropriate assays manual section.

1. **TDx<sup>®</sup> Precision Dispenser**  
(No. 9528-02)



2. **X SYSTEMS<sup>®</sup> Centrifuge Tubes**  
(No. 9527-40) Centrifuge tubes are packaged in quantities of 100.

**Manuals**

The TDxFLx<sup>®</sup> System uses the following manuals:

TDxFLx<sup>®</sup> System Operations Manual

List Number 04A24-51

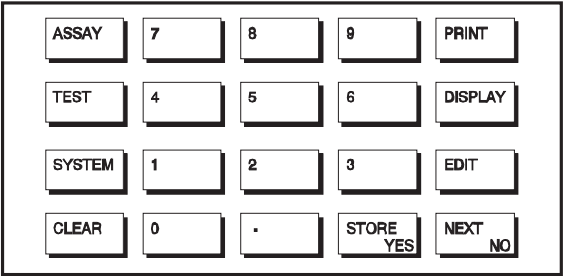
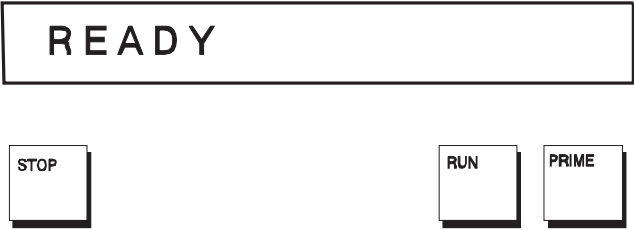
TDx<sup>®</sup>/TDxFLx<sup>®</sup> Systems Assays Manual

List Number 04A24-52

These system manuals are shipped with the instrument.

Keypad Functions

The following is a description of the system status keypad functions of the TDxFLx<sup>®</sup> Analyzer.



System Status Keypad

Command

Function

<b>RUN</b>	Starts assay and calibration runs and some diagnostic checks.
<b>ASSAY RUN</b> (Random Access)	Starts the random-access run regardless of the carousel label. Random-access barcode override is described in <b>Section 3.0 Operation</b> .
<b>ASSAY XX RUN</b> (Batch)	Starts the particular batch assay indicated by the number XX, regardless of the reagent-pack label or the carousel label. Barcode override is described in <b>Section 3.0 Operation</b> .
<b>ASSAY . RUN</b> (Unit Dose)	Starts a unit dose run, regardless of the carousel label. Unit dose barcode override is described in <b>Section 3.0 Operation</b> .
<b>TEST X.X RUN</b>	Starts the instrument specification check, calibration procedure, or diagnostic test specified by the number X.X or X.X.X.
<b>SYSTEM X.X RUN</b>	Starts the system functions.
<b>STOP</b>	Stops any assay, test, system, prime, or printout in progress. Returns the TDxFLx <sup>®</sup> Analyzer to <b>READY</b> .

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<b>PRIME</b>	Moves the boom arm to home then to the waste/wash station. The system then primes the dispenser assembly with buffer. <b>PRIME</b> only functions in the <b>READY</b> state. The carousel returns to home before the prime is initiated. You may press the <b>PRIME</b> key a maximum of three times to initiate the consecutive priming sequence.  <b>NOTE:</b> Automatic primes are initiated if the liquid temperature is too high after an assay.
<b>PRINT or DISPLAY</b>	
<b>PRINT</b>	Advances the paper one line at a time.
<b>ASSAY PRINT</b>	Prints the list of assays programmed in memory.
<b>ASSAY XX PRINT</b>	Prints the parameters for the assay indicated by the assay number (XX).
<b>ASSAY XX.X PRINT</b>	Prints the assay parameter specified by the number (XX.X) along with remaining assay parameters.
<b>SYSTEM PRINT</b>	Prints the system monitors programmed in memory.
<b>SYSTEM X PRINT</b>	Prints the system status indicated by the number (X).
<b>SYSTEM X.X PRINT</b>	Prints the system parameter indicated by the number (X.X) along with the remaining system parameters.
<b>TEST PRINT</b>	Prints the list of diagnostic test categories programmed in memory.
<b>TEST X PRINT</b>	Lists subcategories of diagnostic tests within the major category indicated by the number (X).  <b>NOTE:</b> If <b>DISPLAY</b> is substituted for <b>PRINT</b> in any of the above commands, the data are shown on the display instead of being printed. If the data consist of several lines, the succeeding line can be displayed by pressing <b>NEXT</b> .

ASSAY XX.X EDIT  
SYSTEM X.X EDIT  
TEST X.X.X EDIT

EDIT and STORE

Displays the value requested by the parameter number (XX.X, X.X, or X.X.X). New values are entered by pressing the appropriate numbers on the keypad and stored by pressing **STORE**. The numbers appear on the display as entered, but the new value is not substituted unless the **STORE** key is pressed.

If you must edit another parameter for this assay, system, or test, press **NEXT** until that parameter is displayed. Enter the new value, and press **STORE**.

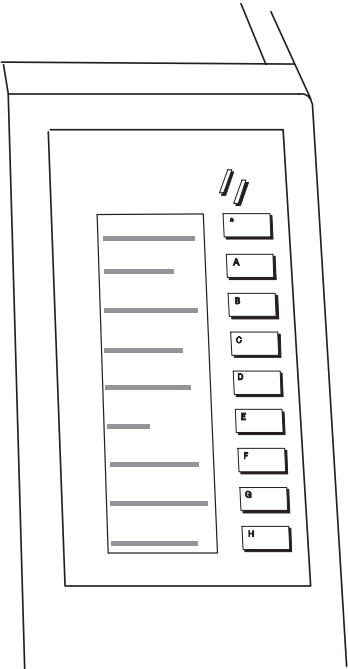
If an error is made when entering a number, press **CLEAR** then enter the correct number.

**NOTE:** If the value is not intended for operator editing, the display shows [WRT PROTECT] and the value will not change.

Reagent Keypad

The reagent keypad is used to select the assays/panels to be run in the random-access mode. This keypad activates when the reagent-barcode reader scans the loaded carousel.

Command	Function
*	Activates the panel mode.
A - H	Displays the assay names and indicates the number of test used [t used = XXX] or test left [t left = XXX].





**TDxFLx<sup>®</sup> System**

For *In Vitro* Diagnostic Use.

Components are designed by Abbott Laboratories for optimal performance as a system. Substitution of reagents, accessories, or instrument components may adversely affect performance and may invalidate any warranty agreements.

Abbott Laboratories does not accept responsibility for the accuracy of any assay results produced by the use of reagents, calibrators, controls, disposables, buffer, or pretreatment manufactured by anyone other than Abbott Laboratories.

**TDxFLx<sup>®</sup> Reagents**

Refer to the Important Note Card included in each reagent pack for the stability of the reagent after application of the Snap Cap. Do not use reagents beyond the expiration date printed on the kit label.

Some reagents contain sodium azide as a preservative. Use accepted guidelines for disposal.

To avoid possible contamination, do not combine the contents of different reagent packs.

Some reagents contain human blood components. Consider all clinical specimens and reagent controls, calibrators, etc., as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.

Some reagents contain human urine. Handle with appropriate care.

Do not freeze reagents unless specified. If reagents are frozen during shipment, contact the **Customer Support Center**.

Abbott Laboratories cannot accept responsibility for the accuracy of any assay results produced by use of reagents manufactured by anyone other than Abbott Laboratories.

**Wedge**

Mix TDxFLx<sup>®</sup> reagent pack(s) by swirling. Place wedge reagent pack(s) into the reagent carousel and place the reagent carousel onto a level worksurface. Hold the carousel firmly and swirl by moving in a circular motion for at least five seconds. **DO NOT INVERT.**

**CAUTION: Inversion of the TDxFLx<sup>®</sup> (wedge) reagent pack(s) may cause liquid entrapment in the snap cap.**

**Batch**

Mix TDx<sup>®</sup>/TDxFLx<sup>®</sup> reagent pack(s) by gentle inversion.

Avoid excessive agitation to prevent foaming which could affect results. If excessive foaming does occur, allow the reagent pack to sit until the foam has dissipated.

Do not leave reagent vials uncapped for prolonged periods of time. Immediately following a run, remove reagents from the TDxFLx<sup>®</sup> System, cap securely, and return them to proper storage conditions.

Place only the reagents to be used on the current run in the instrument.

**CAUTION: Reagent packs not being used for the immediate run must be removed and recapped and returned to proper storage conditions.**

### Unit Dose Reagent Cartridges

Some reagents contain sodium azide as a preservative. Use accepted guidelines for disposal.

Do not use cartridges past their expiration date.

Ensure that the cuvette is securely attached to the unit dose reagent cartridge. To easily attach and prevent breakage of the cuvette, firmly squeeze the cuvette attachment port on the unit dose reagent cartridge with the thumb and forefinger, and release. Attach the cuvette.

Avoid dropping or shaking unit dose reagent cartridges.

Prolonged exposure of individual cartridges to light may be detrimental to assay performance. Store in the light-protective package provided.

Do not puncture foil on the cartridge prior to use.

Some reagents contain human blood components. Consider all clinical specimens and reagent controls, calibrators, etc., as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.

Do not freeze reagents unless specified. If the reagents are frozen during shipment, contact the **Customer Support Center**.

Abbott Laboratories cannot accept responsibility for the accuracy of any assay results produced by use of reagents manufactured by anyone other than Abbott Laboratories.

**Test Sample**

Collect blood samples by venipuncture following the usual precautions for venipunctures. If the sample is obtained through the infusion set, flush the line thoroughly with saline before taking the blood sample. Refer to the appropriate Sample Collection section of the TDx<sup>®</sup>/TDxFLx<sup>®</sup> Systems Assays manual for further information.

With some exceptions (noted in the assays manual as a limitation of the procedure), any anticoagulant may be used to collect plasma for analysis. Serum, as well as plasma, may be used for most assays.

It is very important that the physician be informed of the times of sample collection and dose administration; this information should be supplied to the laboratory with each sample and reported with the results of each test.

Serum and blood samples should be refrigerated upon collection and stored frozen (–20°C or colder) if not analyzed within 24 hours. Complete mixing of each thawed sample is required before analysis. For limitations of sample-storage conditions, refer to the appropriate Sample Collection section of the TDx<sup>®</sup>/TDxFLx<sup>®</sup> Systems Assays manual.

Fibrin threads or large particles which could block the stainless steel probe should not be pipetted or poured into the sample well. After sample transfer, assure there are no bubbles or foam present in the sample well. Remove bubbles or foam prior to the run.

Automatic serum blank readings reduce optical interferences from grossly icteric, hemolyzed, or lipemic samples. The TDxFLx<sup>®</sup> Analyzer automatically subtracts serum blanks before final results are printed, when required by the specific assay mode.

Fluorescein is a constituent of all FPIA and REA<sup>®</sup> reagent systems. Patient samples containing fluorescent compounds may interfere with these methodologies and result in high blank intensity readings and low net intensities. If patient samples cannot be diluted below the maximum background value (XX.20), an alternate methodology should be used.

Urine samples must be collected in clean, previously unused containers. It is recommended that samples should be refrigerated upon collection and stored frozen (–20°C or colder) if not analyzed within 48 hours. Frozen samples must be thawed and mixed thoroughly prior to analysis. Samples containing particulate matter that does not interfere with the accuracy of the dispensing system, will not adversely affect results.

Cerebrospinal fluid (CSF) and amniotic fluid samples should be obtained using standard collection procedures. For limitations of sample and storage conditions, refer to the appropriate assay under Sample Collection and Preparation for Testing Analysis in the TDx<sup>®</sup>/TDxFLx<sup>®</sup> Systems Assays manual.

No known test method offers complete assurance that human body fluid samples will not transmit infection. Therefore, all clinical specimens should be handled as potentially infectious materials. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.

Only human samples have been tested and approved for analysis with the TDxFLx<sup>®</sup> Analyzer.

## Sample Volume

Most assays require a minimum sample volume of 50 µL. Refer to the TDx<sup>®</sup>/TDxFLx<sup>®</sup> Systems Assays manual for the specific sample volume.

## X SYSTEMS<sup>®</sup> Calibrators, Controls

Some calibrators and controls contain sodium azide as a preservative. Use accepted guidelines for disposal.

To avoid possible contamination, do not combine contents of different vials.

Do not use vials beyond their expiration date.

Some calibrators and controls contain human blood components. Consider all clinical specimens and reagent controls, calibrators, etc., as potentially infectious materials. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.

Some calibrators and controls contain human urine. Handle with appropriate caution.

Abbott Laboratories cannot accept responsibility for the accuracy of any assay results produced by use of calibrators and controls manufactured by anyone other than Abbott Laboratories.

## Storage

All TDxFLx<sup>®</sup> System products should be stored as described on the product labeling.

## Disposables: Centrifuge Tubes, Cuvettes, and Sample Cartridges

Ensure all disposables are clean and free of foreign matter before use.

Do not wash and reuse centrifuge tubes, cuvettes, or sample cartridges.

Abbott Laboratories cannot accept responsibility for the accuracy of any assay results produced by using centrifuge tubes, cuvettes, or sample cartridges which have been washed for reuse or are manufactured by anyone other than Abbott Laboratories.

## X SYSTEMS® Dilution Buffer

This product contains sodium azide as a preservative. Use accepted guidelines for disposal.

To avoid possible contamination, do not combine contents of different bottles.

Abbott Laboratories cannot accept responsibility for the accuracy of any assay results produced by use of dilution buffer manufactured by anyone other than Abbott Laboratories.

## TDxFLx® Pretreatment Procedures

Refer to the appropriate sample collection section in the assays manual for information on the required pretreatment of patient samples for specific assays. The required pretreatment steps for assays are different and must be accurately performed to assure precise results.

## Prevention of Azide Formation in Laboratory Plumbing

Most TDxFLx® System reagent products contain sodium azide as a preservative. Sodium azide can form lead or copper azides in laboratory plumbing. These azides may explode on percussion such as hammering on pipes. To prevent formation of lead or copper azide, flush drains thoroughly with water after disposing of solutions containing azide. To remove contamination from old drains suspected of azide accumulation, the following procedure is recommended:

1. Siphon liquid from the trap using a rubber or plastic hose.
2. Fill the trap with 10% sodium hydroxide solution.
3. Allow to stand for 16 hours.
4. Flush well with water.

**TDxFLx<sup>®</sup> Analyzer**

Instrument power should remain on continuously. Refer to **Section 6.0 Troubleshooting** for proper start-up procedures following a power interruption.

Keep the instrument out of direct sunlight and drafts and away from sources of direct heat and moisture. Room temperature should be 15° to 30°C (59° to 86°F).

Allow adequate ventilation space, at least 6" on top, both sides, and back.

Keep all access doors closed to prevent damage to the air heater and photomultiplier tube.

Operate the analyzer on a flat, level surface.

Follow recommended maintenance procedures and schedules outlined in **Section 5.0 Maintenance**.

Keep hands away from the syringes, boom assembly, and probe while the instrument is in operation.

The lamp, lamp housing, air heater, and liquid heater are hot. Allow these components to cool before servicing.

**Electrical**

Follow recommended specifications in **Table 1-1 TDxFLx<sup>®</sup> Analyzer Specifications** and installation procedures outlined in **Section 2.0 Installation**.

**Emergency Shutdown**

Turn the ON/OFF switch, on the rear panel, to the OFF position. To prevent electrical shock or damage to the instrument, disconnect the power cord before servicing.

Results Transmission	<p>Transmissions between the TDxFLx<sup>®</sup> System and a host computer via the RS232 port may experience interferences from external environmental factors such as static or electromagnetic fields.</p> <p>The following precautions will minimize this risk:</p> <ul style="list-style-type: none"><li>• High-quality shielded and grounded cable must be used. To ensure integrity of transmissions, the maximum cable length should be limited to 25 feet.</li><li>• The TDxFLx<sup>®</sup> System, the host computer, and any associated cables should not be placed near any sources of static or electromagnetic radiation. In particular, proximity to electromagnetic interference sources, such as centrifuges, vortex devices, and their power cords, should be avoided.</li><li>• Cable connectors must be firmly seated on the TDxFLx<sup>®</sup> System and the host computer ports and secured with screws.</li><li>• When you are transmitting data using the printer echo feature instead of the spooler feature, no error checking information is provided. Results provided through the host computer should be compared with the TDxFLx<sup>®</sup> printouts for verification of data.</li></ul> <p>Refer to <b>Table 1-1, TDxFLx<sup>®</sup> Analyzer Specifications</b>, for further information on the RS232 port.</p>
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Precision Dispenser	<p>This chemically inert dispenser mechanism can be used for liquids except Hydrofluoric Acid.</p>
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**TDxFLx<sup>®</sup> Snap Caps**

Do not leave snap caps on any reagent packs on the reagent carousel during a run. If the analyzer is run with the snap caps on the reagent pack, probe damage will result.

Replace the snap caps on the reagent pack immediately after removing the pack from the reagent carousel. This minimizes evaporation and potential contamination and protects the integrity of the reagent.

Snap caps should only be used with one reagent pack.

Do not wash and reuse snap caps.

**Waste/Wash Station**

If the station becomes clogged, overflow could damage the TDxFLx<sup>®</sup> System. The following procedure protects the waste/wash station from becoming clogged.

Daily, flush the waste/wash station with approximately 20 mL of deionized water. A wide-mouth, unitary wash bottle is recommended.

**NOTE:** The tip of the bottle should be in the wash cup during this flush.

**Decontamination Procedures**

The TDxFLx<sup>®</sup> System must be decontaminated prior to contacting the probe/electrode assembly, servicing by Field Service Engineers, or return to Abbott Laboratories.

**Probe/Electrode Assembly**

Decontaminate the probe/electrode assembly before servicing or removing the probe. Wear gloves, safety glasses and follow other appropriate biosafety practices. Refer to **Section 5.0 Periodic Maintenance** for the Probe Decontamination procedure. This procedure reduces the potential of any infectious organisms being present on the probe/electrode assembly. The 1% sodium hypochlorite solution (20% household bleach) recommended for decontaminating the probe/electrode assembly has been shown to inactivate infectious agents such as HIV and Hepatitis B. Dispose of probe/electrode in an appropriately marked puncture-resistant container.

**External Instrument Surfaces**

Decontaminate the external surfaces of the instrument by cleaning with a detergent solution to remove any soiling. Then wipe-down with a hospital disinfectant such as 0.5% sodium hypochlorite solution.



### **Specimens and Disposables**

Decontaminate and dispose of all clinical specimens, reagents, controls, calibrators, cuvettes, and other potentially contaminated materials in accordance with local, state and federal regulations governing the treatment of regulated medical waste.

Generally accepted procedures for the treatment of solid, potentially infectious wastes include incineration or autoclaving. If an autoclave is used, the effectiveness of the decontamination cycle should be verified.

### **Waste Container**

Remove the waste container from the instrument before adding disinfectant solution. The addition of a disinfectant to the waste container prior to emptying helps to inactivate infectious organisms that may collect in the waste and thus minimize the risk to personnel who have to handle this material. Sodium hypochlorite and glutaraldehyde solutions have been shown to be effective in inactivating organisms such as HBV, HCV and HIV, and can be used for this purpose. Appropriate personal protective equipment should be worn when these materials are handled.

Do not place the waste container inside the instrument with the disinfectant solution in it.

Empty the waste container and rinse thoroughly with water. Return the container to the proper position.

Do not autoclave the waste container.

### **Spill Clean-Up**

Clean-up spills of potentially infectious materials in accordance with established biosafety practices. A generally accepted procedure for clean-up of such spills is to absorb the spill with toweling or other absorbent material, wipe the area with a detergent solution, and then wipe area with an appropriate hospital disinfectant such as 0.5% sodium hypochlorite.

### **System Components**

Do not use bleach solutions to disinfect carousels, tubing, sample syringes, or valve blocks. Degradation of these components or interference with the assays may occur as a result.

**Decontamination  
Procedures References****Biosafety Practices**

Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910, 1030. Occupational Exposure to Bloodborne Pathogens; Final Rule. 235: 64175-64182, 1991.

National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissues: NCCLS Document M29, Villanova, PA.: NCCLS, 1991.

National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Instrument Biohazards: NCCLS Document I17, Villanova, PA.: NCCLS, 1991.

U.S. Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. HHS Publication (NIH) 88-8395. Washington: U.S. Government Printing Office, May, 1988.

World Health Organization. Laboratory Biosafety Manual. Geneva. World Health Organization, 1983.

**Disinfectants/Spill Clean-Up**

Centers for Disease Control. Recommendations for Prevention of HIV Transmission in Health Care Settings. MMWR 36, Supplement No. 2S, 1987.

Martin LS, McDougal JS, and Loskoski SL. Disinfection and Inactivation of the Human T Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus. J. Infect. Dis., August, 1985; 152(2): 400-403.

Sehulster LM, Hollinger FB, Dreesman GR, and Melnick JL. Immunological and Biophysical Alteration of Hepatitis B Virus Antigens by Sodium Hypochlorite Disinfection. Appl. and Envir. Microbiol., 42: 762-767, 1981.

Bond WW, Favero MS, Peterson NJ, and Ebert JW. Inactivation of Hepatitis B Virus by Intermediate-to-High Level Disinfectant Chemicals. J. Clin. Microbiol., 18: 535-538, 1983.

**Waste**

National Committee for Clinical Laboratory Standards. Clinical Laboratory Hazardous Waste; Proposed Guideline. NCCLS Document GP5-P. Villanova, PA.: NCCLS, 1986.


U.S. Environmental Protection Agency. EPA Guide for Infectious Waste Management. Washington, DC: U.S. Environmental Protection Agency, Publication No. EPA/530-5W-56-014, 1986.

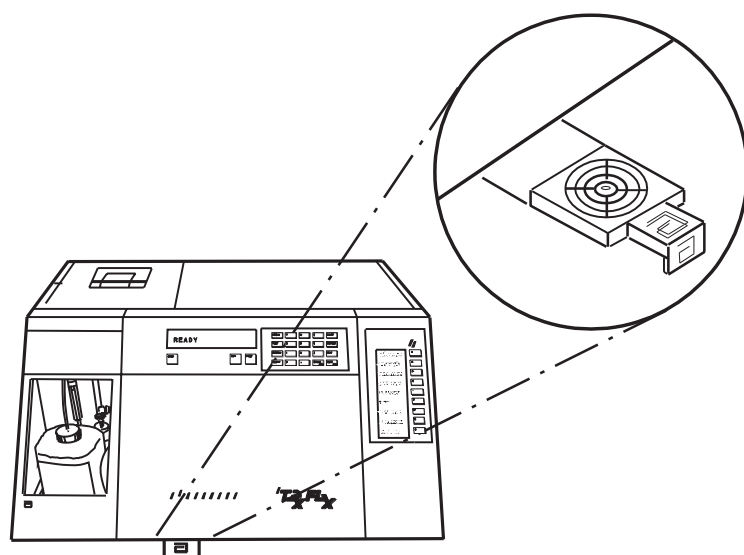
**Introduction**

This section provides instructions for:

- **Component Installation**
- **System Initialization**
- **System Check**
- **Specification Checks**
- **Relocation**

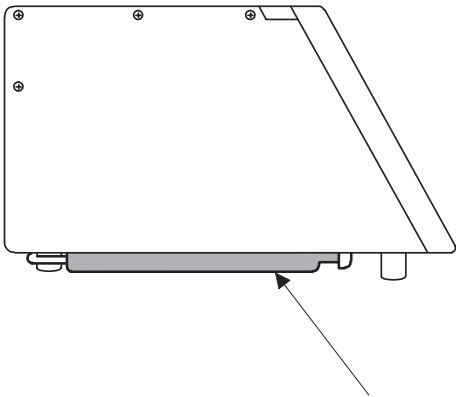
## Component Installation

- Step 1 Install printer paper according to the instructions provided in [Section 5.0 Maintenance](#).
- Step 2 Affix labels to the carousels. Affix a numeric label to the carousel(s) to be used for assay runs and a CAL label to the carousel to be used for calibration runs. For unit dose, affix the UD label to the carousel to be used for assay runs and a CAL label to the carousel to be used for calibration runs. Be sure that the label is centered in the raised frame area.
- Step 3 Make sure the air-fan filter is clean. If necessary, wash the filter as described in [Section 5.0 Maintenance](#). Install the air-fan filter into the instrument by sliding it completely into the bracket under the front of the instrument. Ensure that the  on the filter handle faces up. The handle must be flush with the base of the instrument and not heard rubbing the fan.



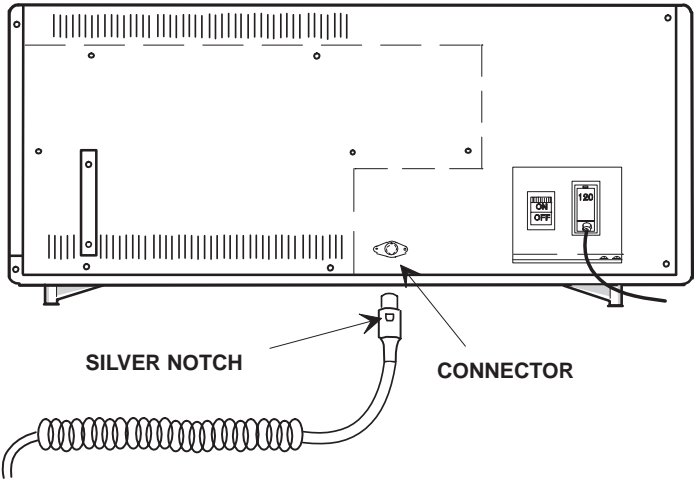
**AIR-FAN FILTER INSTALLATION**

- Step 4    Install the waste container. Slip the waste container under the left side of the TDxFLx<sup>®</sup> System. Ensure that the container retention hook is positioned around the back left leg of the instrument.



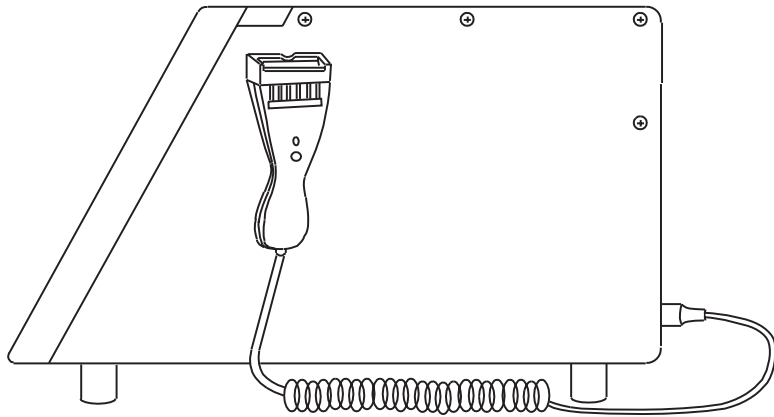
WASTE CONTAINER INSTALLATION

- Step 5    Install the barcode scanner by connecting the cord (silver notch up) into the connector located on the back of the instrument.



CONNECTING BARCODE SCANNER

- Step 6 Remove the magnet adhesive strip cover and mount the barcode scanner on the right side of the instrument.

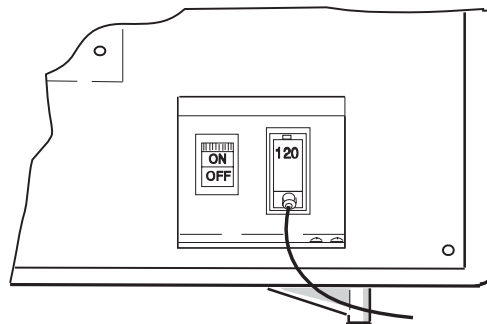


BARCODE SCANNER MOUNTED

- Step 7 Check the outlet voltage to ensure that it matches the voltage set on your instrument and that it is within the specification provided in **Section 1.0 System Description**, Table 1-1 TDxFLx<sup>®</sup> Analyzer Specifications.

**CAUTION:** If the voltage on your instrument needs to be changed, contact the **Customer Support Center** for instructions.

- Step 8 Connect the power cord and turn the power switch to ON.



POWER SWITCH

System Initialization

Step 1 When power is turned on, the display reads:

DATE \_\_ . \_\_ . \_\_

Enter the date as follows:

\_\_ . \_\_ . \_\_

current      current      current

month      day      year

**NOTE:** Each entry must be two digits and must be separated by pressing the “.” key. This character appears in the display as a slash. A valid date must be entered. If a different date format is desired, refer to **step 6 (System 6.11)** under **Specification Checks** for more information.

Step 2 If the date is entered correctly, press **STORE**. If an entry error is made, press **CLEAR** and repeat Step 1. When the date is stored, the display reads:

TIME \_\_ . \_\_ . \_\_

Step 3 Enter the current military (24-hour) time as follows:

\_\_ . \_\_ . \_\_

current      current      current

hour      minute      second

**NOTE:** Each entry must be in two digits and must be separated by pressing the “.” key. This character appears in the display as a colon.

Step 4 If the time is entered correctly, press **STORE**. If an entry error is made, press **CLEAR** and repeat Step 3.

After power-up, the TDxFLx<sup>®</sup> System begins a maximum 5-minute warm-up period. After the warm-up period, the display panel reads:

READY

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**System Check**

- Step 1    Ensure that the waste container has been properly installed. Install the buffer bottle and prime the instrument five times to remove any air bubbles. If air bubbles remain in the dispenser, refer to **Section 6.0 Troubleshooting** under Observed Problems for corrective action.
- Step 2    Print the following system parameters. Press **SYSTEM X PRINT**, with **X** being the system number.
- System 2**   - System Control parameters  
**System 3**   - System parameters  
**System 6**   - Identification parameters  
**System 8**   - Unit dose parameters  
**System 9**   - Shared-pack options  
**System 10** - Reagent carousel parameters
- Verify that the parameters are the same as the printout received with the instrument. If they do not agree, edit by pressing **SYSTEM X.XX EDIT** (enter new value) **STORE STOP**.
- Step 3    To avoid any heater error messages, allow the TDxFLx<sup>®</sup> System to warm up for 30 minutes before performing any specification checks.



Specification  
Checks

The following steps should be performed prior to operation. The instructions for each of the procedures are presented in [Section 5.0 Maintenance](#) unless otherwise noted.

- Step 1 Perform the [Daily Start-Up Procedures](#).\*
- Step 2 Perform a Temperature Check ([Test 2.1](#)).
- Step 3 Perform a Photo Calibration ([Test 3.4](#)).
- Step 4 Perform a Photo Check ([Test 2.2](#)).
- Step 5 Perform a Pipet Check ([Test 2.3](#)).
- Step 6 The following list provides both a listing and explanation of all the instrument programmable options.

Editing

To edit a system parameter press **SYSTEM X.X EDIT** (selection desired) **STORE STOP**. For the selection desired, 0 = off and 1 = on unless otherwise specified.

The following system parameters may be edited, if desired:

- SYSTEM 2.1 -** Beep  
Instrument beeps when numbers are entered on the keypad and when assay or calibration runs are complete.
- SYSTEM 2.2 -** Door Sensor  
Controls door lock sensor.
- SYSTEM 2.3 -** Reset Sample  
Controls automatic resetting of the sample volume following a dilution protocol. The feature is operable for all random access assays, most batch mode assays and all Turbo® Assays. It is not active for HDL Cholesterol, CRP and unit dose assays.
- SYSTEM 2.8 -** Paper-Out  
Overrides the paper-out switch for photo check ([Test 2.2](#)), temperature calibration ([Test 3.1](#)), and photo calibration ([Test 3.4](#)). This option allows the operator to run these tests when the paper supply is low.
- SYSTEM 2.9 -** Data Storage  
Allows the instrument to store or spool data into memory. Refer to the appropriate TDxFLx® RS232C Interface Specification manual for instructions on how to use this feature.

\*This procedure is also presented in [Section 3.0](#).

- SYSTEM 2.10 - Computer Mode**  
Activates the serial output mode. Refer to the appropriate TDxFLx<sup>®</sup> RS232C Interface Specification manual for instructions on how to use this feature.
- SYSTEM 2.11 - Waste Cup**  
Waste cup messages check.  
0 = Off  
1 = Message prompts operator to empty waste container after 25 primes.
- NOTE:** When options 0 and 1 are activated, the NO WASTE CUP message is disabled.  
2 = Prompts operator to empty waste container after 174 primes.
- SYSTEM 6.3 - Operator ID**  
Allows the operator to enter up to a 9-digit operator ID number.
- SYSTEM 6.5 - Reagent Lot #**  
Reagent lot numbers are printed on the reagent load list or assay header printout. This feature is not activated for unit dose or Turbo<sup>®</sup> Assays.
- SYSTEM 6.6 - Patient ID**  
The operator may enter a patient ID (up to ten characters) for each patient sample on a sample carousel. This feature is not activated for calibration runs or unit dose assays.
- SYSTEM 6.7 - Abused Drug Printout (Threshold Print)**  
Controls the type of printout for abused drug assays only. For more details on this option, refer to **Section 3.0 Operation** under the **Batch Calibration** and **Assay Procedures**.

- SYSTEM 6.10 - Printout Format**  
This feature allows three printout format options:
- 0 = By sample carousel location
  - 1 = By patient ID (all results for one patient printed together)
  - 2 = By assay (all results for one assay printed together)
- SYSTEM 6.11 - Date Format**  
This feature allows the operator to choose a different date format. The selections available are:
- 0 = MM/DD/YY
  - 1 = DD/MM/YY
  - 2 = YY/MM/DD
1. To program this feature press **SYSTEM 6.11 EDIT**.
  2. Press the number for the desired format 0, 1 or 2.
  3. Press **STORE STOP**.
  4. Press **SYSTEM 1.1 EDIT**.
  5. Enter the date in the format selected in Step 2.
- SYSTEM 6.12 - Reagent Pack Usage**  
Option to print or display the number of tests used or tests left for a reagent pack.
- 0 = Number of tests used
  - 1 = Number of tests left
- SYSTEM 6.13 - Reagent Loadlist**  
Allows the option to print or not print the reagent loadlist for random access testing. If this feature is turned off, the reagent loadlist will not be displayed on the system status display or printed on the assay printout.
- SYSTEM 6.14 - Sample Loadlist**  
Allows the option to print or not print the sample loadlist at the beginning of a run.
- SYSTEM 7 - Thyroid Feature**  
Refer to the T-Uptake assay insert in the assays manual.

SYSTEM 9 -	Shared Pack Options	
	This system allows optional sharing of reagent packs. Free drug assays may be run in the batch mode of operation.	
	System Parameter	
	9.1 ESTRL	0 = off, 1 = on
	9.2 PHEN	0 = off, 1 = on
	9.3 CARB	0 = off, 1 = on
	9.4 VALPR	0 = off, 1 = on
	9.5 CHOLE	0 = off, 1 = on
	Batch	
	When the assay run is initiated, the instrument display shows the primary assay name. If <b>STORE</b> is entered, the primary assay is run. If <b>NEXT, STORE</b> is entered, the secondary assay is run.	
SYSTEM 11 -	Batch reagent pairs:	
	PRIMARY	SECONDARY
	44 Tot Estriol	66 Free Estriol
	04 Phenytoin	26 Free Phenytoin
	09 Carb	32 Free Carb
	08 Val Acid	17 Free Val Acid
	36 Chol	42 HDL Chol
	Panels	
	Refer to <b>Section 3.0 Operation</b> under Random Access Panel Procedure for information.	

- Step 7 Print the assay parameters for the assays to be run. Press **ASSAY XX PRINT**, with **XX** being the assay number.
- Step 8 Check the parameters printed against those listed in the assay manual insert or kit enclosure. Ensure that the parameters are identical.
- NOTE:** Information contained in a kit enclosure (activation letter, important note, etc.) *always* supersedes assay manual inserts.
- Step 9 If the parameters match, proceed with installation. If the parameters do not match, edit the instrument parameters to match those in the assay manual insert or kit enclosure. Press **ASSAY XX.X EDIT** (enter new value) **STORE STOP**.
- Step 10 LOLIM and HILIM values can be edited to flag results as LOW or HI if they fall outside these programmed values. For abused drug assays, the LOLIM parameter will read BKG FAC and the HILIM parameter is the THRSHLD concentration. Refer to **Section 3.0 Operation** under Assay Parameters for more information. LOLIM and HILIM assay parameters may be edited as follows:
- LOLIM - Press **ASSAY XX.3 EDIT**, enter low limit value, press **STORE STOP**.
- HILIM - Press **ASSAY XX.4 EDIT**, enter high limit value, press **STORE STOP**.
- Step 11 Run calibration curves for the assays to be performed.
- Step 12 Complete and return the installation report.

**Relocation**

If you must relocate your TDxFLx<sup>®</sup> System after the initial installation, ensure that the new location accommodates all electrical and environmental specifications. For specification information, refer to [Section 1.0 System Description, Table 1-1 TDxFLx<sup>®</sup> Analyzer Specifications](#).

- Step 1 Turn the power switch off and disconnect the power cord.
- Step 2 Carefully remove the waste container from underneath the instrument.
- Step 3 After reconnecting the power cord and turning the power on, initialize the TDxFLx<sup>®</sup> System as described previously. If the power interruption is longer than 30 minutes, allow the system to warm up for 30 minutes after power is restored. This procedure minimizes heater error messages.
- Step 4 Reinstall the waste container.
- Step 5 Prior to operation, perform a [Photo Check \(Test 2.2\)](#).
- Step 6 When initiating the first assay run, validate one level of control (H, M or L) for the reagent system being used. If the control is out of range, call the [Customer Support Center](#) for further instructions.

If the printed circuit board retainer has been removed, reseal the printed circuit boards as described in [Section 5.0 Maintenance](#) under [Circuit Board Removal and Replacement](#).

**Introduction**

This section provides details on the following information:

- [Quality Control](#)
- [Daily Start-Up](#)
- [Programmable Options](#)
- [Assay Parameters](#)
- [Calibration Overview](#)
- [Dilution Protocol](#)

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**Quality Control**

Quality control procedures recommended to ensure optimal assay and instrument performance include:

1. Perform all maintenance procedures presented in **Section 5.0 Maintenance**.
2. Verifying quality control requirements in the assay specific insert.



**Daily Start-Up**

These procedures should be performed at the start of each day. If the system is used on multiple shifts, perform the procedures at the start of each 8-hour shift.

1. Waste Container - Empty and wash the container and return it to its proper position.
2. Probe Inspection and Wash - Refer to **Section 5.0 Daily Maintenance** for instructions.
3. Dispense Assembly Inspection - Raise the dispense cover door and press **PRIME** three times.

Inspect for air bubbles and leaks in all tubing, syringes and connections. To remove air bubbles, refer to **Section 6.0** under **Observed Problems**.

Inspect for dried buffer salts or liquid buffer in and around all dispenser components. Replace as needed.

4. Waste/Wash Station Cleaning - Clean the waste/wash station by flushing it with approximately 20 mL of distilled water. Use a wide-mouth, unitary wash bottle for this procedure. Place the tip of the wash bottle into the waste/wash station and flush thoroughly.
5. Unit Dose Probe Position - Verify probe position daily at the completion of a run. If the puncture marks in the foil are not correct, refer to **Section 5.0 Periodic Maintenance** section for unit dose probe positioning.
6. Maintenance Log - Make appropriate entries.

**Programmable Options**

The following list provides both a listing and explanation of all the instrument programmable options.

**Editing**

To edit a system parameter press **SYSTEM X.X EDIT** (selection desired) **STORE STOP**. For the selection desired, 0 = off and 1 = on unless otherwise specified.

The following system parameters may be edited, if desired:

- |                      |  |
|----------------------|--|
| <b>SYSTEM 2.1 -</b>  | Beep<br>Instrument beeps when numbers are entered on the keypad and when assay or calibration runs are complete.   |
| <b>SYSTEM 2.2 -</b>  | Door Sensor<br>Controls door lock sensor.  |
| <b>SYSTEM 2.3 -</b>  | Reset Sample<br>Controls automatic resetting of the sample volume following a dilution protocol. The feature is operable for all random access assays, most batch mode assays and all Turbo <sup>®</sup> Assays. It is not active for HDL Cholesterol, CRP and unit dose assays. |
| <b>SYSTEM 2.8 -</b>  | Paper-Out<br>Overrides the paper-out switch for photo check (Test 2.2), temperature calibration (Test 3.1), and photo calibration (Test 3.4). This option allows the operator to run these tests when the paper supply is low.   |
| <b>SYSTEM 2.9 -</b>  | Data Storage<br>Allows the instrument to store or spool data into memory. Refer to the appropriate TDxFLx <sup>®</sup> RS232C Interface Specification manual for instructions on how to use this feature.  |
| <b>SYSTEM 2.10 -</b> | Computer Mode<br>Activates the serial output mode. Refer to the appropriate TDxFLx <sup>®</sup> RS232C Interface Specification manual for instructions on how to use this feature.   |
| <b>SYSTEM 2.11 -</b> | Waste Cup<br>Waste cup messages check.<br>0 = Off<br>1 = Message prompts operator to empty waste container after 25 primes.  |

**NOTE:** When options 0 and 1 are activated, the NO WASTE CUP message is disabled.

2 = Prompts operator to empty waste container after 174 primes.

- SYSTEM 6.3 -** Operator ID  
Allows the operator to enter up to a 9-digit operator ID number.
- SYSTEM 6.5 -** Reagent Lot #  
Reagent lot numbers are printed on the reagent loadlist or assay header printout. This feature is not activated for unit dose or Turbo<sup>®</sup> Assays.
- SYSTEM 6.6 -** Patient ID  
The operator may enter a patient ID (up to ten characters) for each patient sample on a sample carousel. This feature is not activated for calibration runs or unit dose assays.
- SYSTEM 6.7 -** Abused Drug Printout (Threshold Print)  
Controls the type of printout for abused drug assays only. For more details on this option, refer to **Batch Calibration** and **Assay Procedures** in this section.
- SYSTEM 6.10 -** Printout Format  
This feature allows three printout format options:  
0 = By sample carousel location  
1 = By patient ID (all results for one patient printed together)  
2 = By assay (all results for one assay printed together)
- SYSTEM 6.11 -** Date Format  
This feature allows the operator to choose a different date format. The selections available are:  
0 = MM/DD/YY  
1 = DD/MM/YY  
2 = YY/MM/DD
1. To program this feature press **SYSTEM 6.11 EDIT**.
  2. Press the number for the desired format 0, 1 or 2.
  3. Press **STORE STOP**.
  4. Press **SYSTEM 1.1 EDIT**.
  5. Enter the date in the format selected in Step 2.

- SYSTEM 6.12 -

Reagent Pack Usage  
Option to print or display the number of tests used or tests left for a reagent pack.  
  
0 = Number of tests used  
1 = Number of tests left
- SYSTEM 6.13 -

Reagent Loadlist  
Allows the option to print or not print the reagent loadlist for random access testing. If this feature is turned off, the reagent loadlist will not be displayed on the system status display or printed on the assay printout.
- SYSTEM 6.14 -

Sample Loadlist  
Allows the option to print or not print the sample loadlist at the beginning of a run.
- SYSTEM 7 -

Thyroid Feature  
Refer to the T-Uptake assay insert in the assays manual.
- SYSTEM 9 -

Shared Pack Options  
This system allows optional sharing of reagent packs. Free drug assays may be run in the batch mode of operation.  
  
System Parameter  
9.1 ESTRL      0 = off, 1 = on  
9.2 PHEN      0 = off, 1 = on  
9.3 CARB      0 = off, 1 = on  
9.4 VALPR      0 = off, 1 = on  
9.5 CHOLE      0 = off, 1 = on  
  
Batch  
  
When the assay run is initiated, the instrument display shows the primary assay name. If **STORE** is entered, the primary assay is run. If **NEXT**, **STORE** is entered, the secondary assay is run.  
  
Batch reagent pairs:  

PRIMARY	SECONDARY
44 Tot Estriol	66 Free Estriol
04 Phenytoin	26 Free Phenytoin
09 Carb	32 Free Carb
08 Val Acid	17 Free Val Acid
36 Chol	42 HDL Chol
- SYSTEM 11 -

Panels  
Refer to the **Random Access** section under Panel Procedure for information.

## Assay Parameters

A list of assays currently in TDxFLx<sup>®</sup> System memory can be obtained by pressing **ASSAY PRINT**. The instrument prints a list of assays and their numbers. Retain this list to avoid the need to perform this step each time an assay number is required.

### Parameters Listing

To list parameters for an assay, use this procedure:

1. Determine the assay number on the list of assays.
2. Press **ASSAY XX PRINT**, with XX being the assay number. The analyzer prints the parameters for the selected assay. These 27 parameters set the specific characteristics of each individual assay. Explanation of these parameters follows.
3. Check the parameters printed against those listed in the assay manual insert or kit enclosure. Ensure that the parameters are identical.

**NOTE:** Information contained in a kit enclosure (activation letter, important note, etc.) **always** supersedes assay manual inserts.

4. If the parameters match, proceed with the assay. If the parameters do not match, edit the instrument parameters to match those in the assay manual insert or kit enclosure.

### Parameter Explanation

The following list provides both a listing and an explanation of all assay parameters.

- |    |          |  |
|----|----------|--|
| .1 | SPL VOL* | Final volume of sample in cuvette in microliters.  |
| .2 | SPL REP  | <p>Sample replication, 1-20. In the batch mode of operation, if the SPL REP is programmed for a value greater than one, the system prints an average of the replicates, in addition to the individual sample value.</p> <p>This parameter only functions on batch runs and random access calibration runs.</p> |

\*Values for SPL VOL and CAL VOL are equal for most assays. See the assays manual for parameters.

.3	LOLIM**	Low concentration for flagging samples below therapeutic or normal range. For abused drug assays, this parameter is the BKG FAC.
.4	HILIM**	High concentration for flagging samples above therapeutic or normal range. For abused drug assays, this parameter is the THRSHLD concentration.
.5	CAL VOL*	Final volume of calibrator in cuvette in microliters.
.6	CAL REP	Calibrator replicates (1-3).
.7	CONC A	A Calibrator concentration.
.8	CONC B	B Calibrator concentration.
.9	CONC C	C Calibrator concentration.
.10	CONC D	D Calibrator concentration.
.11	CONC E	E Calibrator concentration.
.12	CONC F	F Calibrator concentration.

\*Values for SPL VOL and CAL VOL are equal for most assays. See the assays manual for specific assay parameters.

\*\*LOLIM and HILIM values can be edited to acceptable therapeutic or normal range values for each assay. Concentration results are flagged as LOW or HI if they fall outside these programmed values.

- .13

UNITS

Code for concentration units. The following units are available by code number:

Code	Unit	Definition
0	µg/mL	Micrograms/Milliliter
1	ng/mL	Nanograms/Milliliter
2	µmol/L	Micromoles/Liter
3	nmol/L	Nanomoles/Liter
4	mmol/L	Millimoles/Liter
5	mol/L	Moles/Liter
6	µg/dL	Micrograms/Deciliter
7	mg/dL	Milligrams/Deciliter
8	g/dL	Grams/Deciliter
9	g/L	Grams/Liter
10	mEq/L	Milliequivalents/Liter
11	Units/L	Units/Liter
12	mUnits/µL	Milliunits/Microliter
13	I Units/L	International Units/Liter
14	%	Percentage
15	mg/L	Milligrams/Liter
16	T-Uptake Units	T-Uptake Units
17	(user defined)	User Defined Units
18	mP	Millipolarization Units
19	mg / g	Milligrams/Gram
- .14

CRV FIT

Data reduction for calibration curve (2 through 21).
- .15

MX DEV

Maximum range of millipolarization values or percent fluorescence intensities allowed on calibrator replicates.
- .16

MN POLA\*\*\*

Minimum millipolarization allowed for the A calibrator during a calibration.

\*\*\*These parameters cannot be edited. If an attempt is made to edit them, the message [WRT PROTECT] appears in the display. Press **STOP** to continue operation.

.17	MN SPAN	Minimum millipolarization or percent fluorescence intensity span allowed between A and F calibrators during a calibration.
.18	MODE	Pipetting sequence.
.19	GAIN***	Relative value to set PMT voltage.
.20	MX BKG	Maximum background intensity allowed before flagging occurs. For abused drug assays, if parameter .3 BKG FAC is edited or whenever a Pipet Check is performed, then MX BKG (.20) = BKG FAC (.3) × MN TR (.21).
.21	MN TR***	Minimum allowed net intensity reading before flagging occurs. (This parameter automatically updates when a <b>Pipet Check procedure</b> is run.)
.22	BA DTE***	Date of last batch calibration. (If zeros appear for this parameter, no calibration curve is stored for the assay.)
.23	BA TME***	Time of last batch calibration. (If zeros appear for this parameter, no calibration curve is stored for the assay.)
.24	RA DTE***	Date of last random access calibration. (If zeros appear for this parameter, no calibration curve is stored for the assay.)
.25	RA TME***	Time of last random access calibration. (If zeros appear for this parameter, no calibration curve is stored for the assay.)

\*\*\*These parameters cannot be edited. If an attempt is made to edit them, the message [WRT PROTECT] appears in the display. Press **STOP** to continue operation.



- .26 UD DTE\*\*\* Date of last unit dose calibration. (If zeros appear for this parameter, no calibration curve is stored for the assay.)
- .27 UD TME\*\*\* Time of last unit dose calibration. (If zeros appear for this parameter, no calibration curve is stored for the assay.)

\*\*\*These parameters cannot be edited. If an attempt is made to edit them, the message [WRT PROTECT] appears in the display. Press **STOP** to continue operation.

### Parameter Editing

1. To edit an assay parameter, select the assay number and the number of the parameter to be changed. For example, 4.1 is the parameter for Phenytoin sample volume.
2. Press **ASSAY XX.X EDIT** (enter the new value) **STORE**.
3. If another parameter is to be edited for the same assay, press **NEXT** until the parameter to be edited is in the display, (enter the new parameter value), press **STORE**.
4. After editing is complete, press **STOP**. Then press **ASSAY XX.X PRINT** to get a printout of the specific new assay parameter value or **ASSAY XX PRINT** to obtain a complete listing of all parameters. Check that the new parameter values are appropriate for the assay.

### Changing Concentration Units

To report results in concentration units other than the units listed on the package of calibrators for that assay, the following changes must be made to the assay parameters:

1. Edit the units to the desired concentration by using the code number designated in assay parameter (.13). This only changes the units of concentration that print on the header.
2. Mathematically convert the concentration of each calibrator (B-F) to the new units of concentration.

Example: To convert from  $\mu\text{g/mL}$  to  $\mu\text{M/L}$  calculate the following:

$$\frac{(\text{conc. in } \mu\text{g/mL}) (1000 \text{ mL/L})}{\text{molecular weight}} = \mu\text{M/L}$$

3. Edit the new concentration for each calibrator into assay parameters (.8) through (.12). Edit the LOLIM (.3) and HILIM (.4) parameters. For abused drug assays, LOLIM (.3) = \*BKG FAC and HILIM (.4) = THRSHLD.

\*Do not edit for abused drug assays. The BKG FAC is used with the MN TR (.21) to calculate an instrument specific MX BKG (.20).

4. Calibrate the assay.

**NOTE:** Concentration units for some assays cannot be changed. Refer to the specific assay procedure section in the assays manual.

Calibration Overview

The following paragraphs present calibration information the operator may need before performing a calibration or reading the printouts.

Calibration Criteria

Before the microprocessor performs the curve fit routine, the raw data from the calibrators are verified as listed below to be sure the criteria are met. When a curve fit criterion is not met, an error message will be printed on the result tape and the curve will not be stored. Any remaining checks will not be performed.

Criterion	Printed Error Message if Criterion is Not Met
Correct number of replicate samples of calibrators is six times assay parameter XX.6 CAL REPS.	CALIBRATION ABORTED or CAL REPS INCORRECT FOR CALIBRATION
Background fluorescence intensity is less than or equal to assay parameter XX.20 MX BKG.	BACKGROUND TOO LARGE
Net fluorescence intensity (NET I) is equal to or greater than assay parameter XX.21 MN TR.	NET I TOO SMALL
Net fluorescence intensity (NET I) is less than 25.5 times assay parameter XX.21 MN TR.	NET I LARGE
Reproducibility of calibrator replicates within specified range of mP or percent fluorescence intensity (assay parameter XX.15 MX DEV) when run in duplicate or triplicate.	RANGE TOO LARGE
Polarization of calibrator A is equal to or greater than assay parameter XX.16 MN POLA. T-Uptake: Specification applies to F calibrator.	P 0 TOO SMALL

Criterion	Printed Error Message if Criterion is Not Met
Difference in polarization or percent fluorescence intensity between the A and F calibrators is equal to or greater than assay parameter XX.17 MN SPAN. For unit dose, the spans between A and B, B and C, C and D, D and E, E and F are checked. A check is also made to ensure the millipolarization of the A calibrator does not exceed the programmed value. These span differences will be noted as CRV FIT XXX, with XXX signifying a number. Definition of this CRV FIT # is in <a href="#">Section 6.0 Troubleshooting</a> .	SPAN LESS THAN MIN SPAN
Polarization or percent fluorescence intensity of calibrators decreases with increasing concentration except for curve fits 5 and 6 (assay parameter XX.14 CRV FIT), where polarization or percent fluorescence intensity increases with concentration.	SPLS NOT MONOTONIC

If the calibration meets the instrument stored calibration criteria, the calibration curve will be stored in memory until another calibration curve replaces it. Only the most recent calibration curve is held in memory.

**Calibration Acceptability Criteria (Operator)**

The operator verifies acceptability of a calibration curve by three criteria:

1. The PERR (polarization error) or ERR (percent error) values must be within the acceptable range indicated in the assay manual insert.
2. The RMSE (root mean squared error) must be within the acceptable range indicated in the assay manual insert.
3. Each level of control must be within the acceptable ranges indicated in the assay manual insert.

If any of these values are out of range, determine the cause and recalibrate, if necessary. Refer to [Section 6.0 Observed Problems](#) under Calibration Fails to Meet Specification.

### When to Recalibrate

Recalibration is required when:

- The **memory circuit board (Board #2)** is replaced.
- An assay activation (new reagent pool) is issued.

Recalibration may be necessary when:

- Assay control values fall outside of the acceptable range specified in the specific assay section of the assay manual insert.
- PERR, ERR, or RMSE values are out of specification. Refer to **Calibration Verification**.
- A new lot number of reagent is used.
- A new lot number of buffer is used.
- Any dispense component is replaced.
- Any instrument calibration procedure is performed.
- A wide variation in room temperature is experienced.

To determine whether recalibration is required, each reagent system should be checked by assaying the controls L, M, and H. If the control results are within range, patient results may be run without need for recalibration. If the control results are not within range for a particular assay, refer to **Section 6.0** under Observed Problems. It may be necessary to recalibrate that assay before reporting any patient results.

## Dilution Protocol

The dilution protocol procedure can be used to analyze a sample result when the concentration of that sample prints a HI instead of a numerical result. Dilution protocol is only available for some assays. Refer to the specific assay manual insert for dilution instructions.

1. Introduce sample into a sample cartridge on the sample carousel.
2. Refer to the assay list printout. If one is not available, press **ASSAY PRINT**. Note the assay number for the assay you are performing.
3. Press **ASSAY XX.1 EDIT**. Divide the [SPL VOL] displayed by the desired dilution ratio.
4. Enter the desired sample volume value (i.e., 1 divided by 2 =.5; enter **.5**) and then **STORE STOP**.
5. Press **RUN**. At the end of the run, polarization and calculated concentration, which the analyzer multiplies by the dilution ratio, are printed.

**NOTE:** If RST SPL ([System 2.3](#)) is set to 1, the sample volume is automatically set by the analyzer to the value of the calibration volume at the completion of the dilution protocol. This feature is not operable with HDL Cholesterol and CRP assays.

Otherwise, sample volume must be manually returned to its original value as follows:

1. Press **ASSAY XX.1 EDIT**.
2. Enter the original sample volume and press **STORE STOP**. The instrument returns to operational status.

**Random Access**

This section details all operating procedures for the random access mode of operation. The procedures are presented in the following order:

- Initialization Checks
- Assay Process Sequence
- Calibration Procedure
- Assay Procedure
- Panel Testing Overview
- Panel Procedure
- Printout Options
- Barcode Override

**Initialization Checks**

Prior to testing in the random access mode of operation, the TDxFLx<sup>®</sup> System performs seventeen initialization checks. After the RUN key is pressed, the following sequence occurs:

1. The reagent carousel locates its home position. If the reagent carousel sensor senses the home flag, the system assumes that the run is in random access format.
2. The system checks for a valid date.
3. The buffer sensor verifies that sufficient buffer is present.
4. The software checks for presence of the waste container and for number of primes performed since the last “**CHECK WASTE CUP**” message was displayed and printed.
5. The syringe and valve movement and home positions are checked.
6. The system checks the horizontal and vertical movement of the boom arm as it seeks the R-Boom and Z-Boom home positions.
7. The TDxFLx<sup>®</sup> System checks for the presence of the sample carousel and verifies that the sample carousel is locked.
8. The boom-arm barcode reader reads the sample carousel label and determines the type of run.
9. The reagent carousel barcode reader reads all of the reagent wedges and performs liquid sensing on each wedge. The liquid sensing is followed by an automatic probe washing.
10. The reagent carousel loadlist is printed. A prompt to edit, if necessary, follows the list.
11. The sample loadlist is prompted by the system and entered by the operator. The sample loadlist is then printed and followed by a prompt to edit if necessary.
12. The door sensor checks to see that the door is closed.
13. The cuvette sensor counts cuvettes by reflectance and looks for missing or extra cuvettes.
14. The lamp is turned on, and the intensity checked.
15. The ambient temperature is checked.
16. The syringe and valve movement and home positions are checked.
17. The thermal detector verifies that the cuvette surface temperature is 35°C.



## Assay Process Sequence

The process sequence for a random access assay occurs automatically after the analyzer door is closed, the RUN key is pressed, and the system has passed all initialization checks. The sequence for a carousel of 20 consists of the following steps:

- Step 1 The sample carousel moves sample number 1 to the dispense axis. The reagent carousel moves accordingly to position the respective reagent pack on the dispense axis.
- Step 2 The first dispense cycle begins. The appropriate reagent is dispensed, and the sample is diluted for background reading if required. The display reads:

REV 1 PIPETTING

- Step 3 As the sample carousel and reagent carousel rotate during Rev 1 Pipetting and the first cuvette reaches the optical path, a background intensity reading is taken and stored in memory. The display reads:

BLANK READING

- Step 4 After Rev 1 Pipetting and as blank readings continue, the first sample position is returned to the dispense axis and the second dispense cycle begins. The display reads:

REV 2 PIPETTING

- Step 5 After Position 19 has been blank read and Position 9 has completed Rev 2 Pipetting, sample number 1 is rotated to the optical path where a final intensity reading is taken. The display reads:

FINAL READING

- Step 6 The sample carousel rotates back to Position 20, completes blank reading and Rev 2 Pipetting on Position 10. Cuvette number two is then rotated to the optical path where a final intensity reading is taken. The display reads:

FINAL READING

The display alternates between REV 2 PIPETTING and FINAL READING until Rev 2 Pipetting is completed for all samples.

- Step 7 When Rev 2 Pipetting is completed and Position 12 completes its final read, final intensity readings are corrected for background intensities. Polarization or percent intensity values, depending on assay technology, are calculated and converted to the appropriate concentration units. Results for Position 1 are then printed.
- Step 8 The sample carousel rotates and the display alternates between [INCUBATING] and [FINAL READING], while printing results for positions 2, 3, and so on through 9. This process continues until all remaining sample intensities are read.
- Step 9 Once all samples are read, results for positions 10 - 20 are quickly printed.
- Step 10 The paper supply is checked.
- Step 11 The display reads:

DONE REMOVE RPAK

the system beeps and then displays

READY

The reagent display is cleared.

If the carousel is not removed within 5 minutes following the completion of the run, the instrument will beep and display

REMOVE CAROUSEL

## Calibration Procedure

The following paragraphs present the step-by-step procedure for performing a random access calibration run.

### System Set-Up

- Ensure that all daily maintenance has been performed if this is the first run of the shift. Refer to **Section 5.0** for maintenance procedures.
- Ensure that the **batch-pack adapter** has been removed.
- Ensure that assay parameter .6 CAL REPS is 2. Press **ASSAY XX.6 DISPLAY**. If it is 2, press **STOP**; if not, press **EDIT 2 STORE STOP**.
- The TDxFLx<sup>®</sup> System stores a calibration curve for each assay. The random access calibration curves are separate and distinct from the calibration curves stored for the batch and unit dose versions of the same assay. Therefore, prior to running an assay, the instrument must be calibrated for that assay in the mode of operation being run.
- Program parameter options as desired. Refer to **Programmable Options** in the Introduction section for details.

### Preparing the Calibration Carousel

1. Select a calibration carousel.
2. Load 15 sample cartridges and cuvettes. Begin with Position 1 and continue sequentially. Do not skip a position.
  - a. Ensure that all cuvettes are right side up.
  - b. Ensure that all disposables are clean and free of foreign matter before use.
3. Lock cuvettes into position by turning the locking mechanism clockwise until it clicks.
4. Invert the calibrator pack gently five times. Pipette in duplicate a minimum of 50  $\mu$ L for most assays, (refer to the assays manual for specific sample volume), of calibrator A-F into sample wells 1 through 12. Avoid splashing, foaming, or bubbling. Recap calibrator vials and return pack to proper storage, as described on the label.
5. Invert the control pack gently five times. Pipette a minimum of 50  $\mu$ L of H, M, and L controls into sample wells 13 through 15. Avoid splashing, foaming, or bubbling. Positions 16 through 20 are available for patient samples.

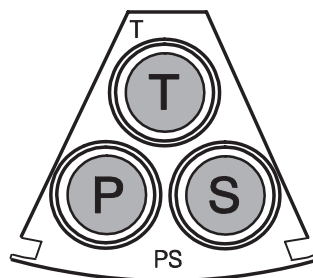
**NOTE:** If the Display Data option (System 4.2) is being used, do not run any samples (unknown or controls) after the last calibration because they will not appear in the display.

Recap each control vial as it is used and return the pack to proper storage as described on the label.

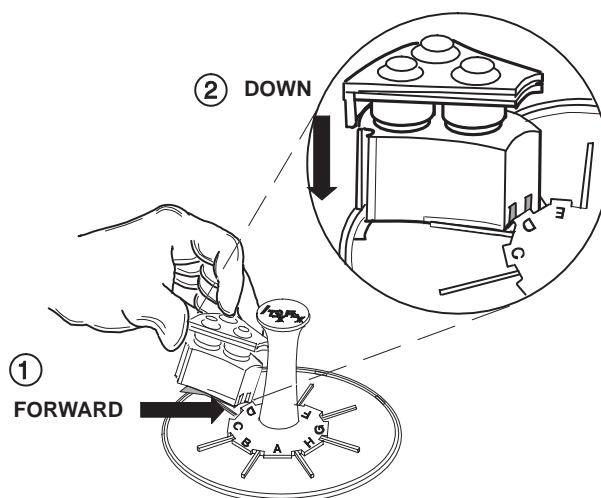
6. Inspect the sample wells for bubbles. Remove any bubbles with applicator sticks. Use a different applicator stick for each sample.

### Preparing the Reagent Carousel

7. Select the appropriate wedge reagent pack for the assay to be calibrated. Verify that the S, T, and P vials are in the correct location.



8. Snap the wedge reagent pack onto the reagent carousel in any position. To insert:

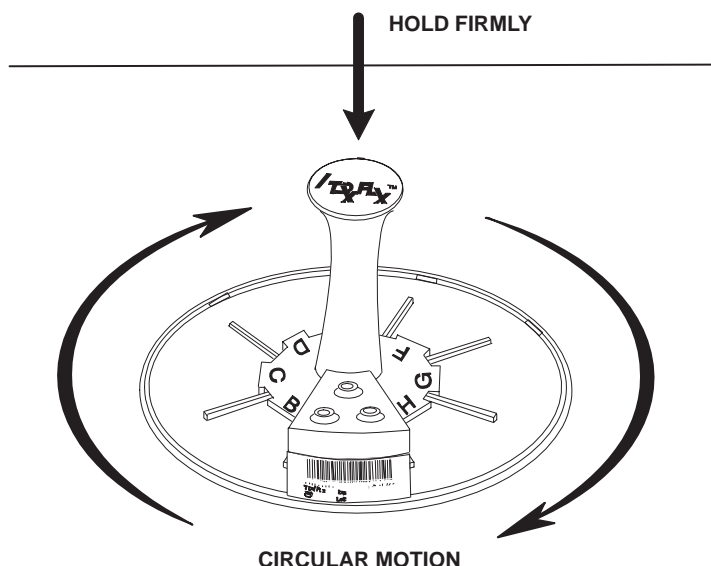


- a. Push the foot at the narrow end of the wedge under the letter tab on the carousel.
- b. Press the wide end of the wedge down firmly until it is even with the edge of the carousel rim.
- c. When positioned correctly, the wedge cannot be removed from the carousel by lifting straight up.

Place only the wedge reagent pack to be used for the calibration run on the carousel.

9. Mix by swirling. Place the reagent carousel onto a level surface. Hold the carousel firmly and swirl by moving in a circular motion for at least five seconds. **Do not invert.**

**CAUTION:** Inversion of the wedge reagent pack(s) may cause liquid entrapment in the snap cap.



10. Remove and discard the vial caps after the initial use of the wedge reagent pack. Following the initial use, seal vials with the snap cap provided with the wedge reagent pack. Place snap caps upside down on a storage container or surface after they are removed.

**CAUTION:** Reagent packs not being used for the immediate run must be removed, recapped and returned to proper storage conditions.

11. Inspect the vials for bubbles. Remove any bubbles with applicator sticks. Use a different applicator stick for each vial.

### Run Calibration

12. Insert the reagent carousel into the analyzer.
13. Place the loaded calibration carousel into the instrument. Close the carousel access door.
14. Press **RUN**.
15. If the instrument is not programmed to record operator ID (**System 6.3** = 0), go to Step 16. If it is programmed to record this number, the display reads:

OP ID?

Enter the ID number using the barcode scanner or the numerical keypad for this input. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

16. Steps 17 and 18 are activated under specific circumstances. In most cases, these two steps are skipped by the instrument. If they are skipped, proceed directly to **Step 19**. If not, then perform these steps; the instrument prompts for the necessary input.
17. If the boom-arm barcode reader fails to detect the sample carousel barcode label properly, the instrument must be programmed for the type of run to perform. In this instance, the display reads:

CALIBRATION?

Press **STORE** and continue with Step 18.

18. If the instrument detects a new/unused wedge reagent pack, the display reads:

RGT # ? \_ \_ \_ \_ \_ \_ \_ \_

Enter the corresponding lot number of the wedge reagent pack and press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

The lot number prompt is only activated the first time a new/unused wedge reagent pack is detected. The instrument skips this step after a wedge reagent pack is initialized into the system.

19. If the instrument is not programmed to record the reagent loadlist (**System 6.13** = 0), go to Step 20. If the instrument is programmed to record this information, a list of the reagents loaded on the reagent carousel is printed. Corresponding assay names and the number of tests used (or tests left) on that wedge reagent pack are also displayed on the reagent display. The display reads:

REAGENT LIST OK?

If the reagent list is correct, press **STORE** and proceed to Step 20.

If the reagent list is incorrect, press **NEXT**. If there were unsuccessful reads (caused by barcode fail or empty position on the reagent carousel), the carousel rotates and positions the first wedge reagent pack that had an unsuccessful read at the 5 o'clock position. This position is indicated by an arrow on the baseplate.

At this point the system enters barcode override. Repeat this step for each unsuccessful read.

Refer to the **barcode-override procedures** for additional information.

If the loadlist must be edited in order to replace a wedge reagent pack, press **STOP**. Then remove the carousel, make the necessary changes, and begin the run sequence again.

**CAUTION:** Do not remove the reagent carousel without first pressing the **STOP** key.

20. Close the carousel access door. Verify that the correct assay name and the word [CALIBRATION] displays.

**NOTES:** After entering a valid reagent loadlist the instrument stores the list temporarily. If the run is aborted, the display reads [SAME RGT CRSL?] when restarting the run.

If the configuration of the reagent carousel remains the same, press **STORE** for the message to accept the list.

If the configuration is different, press **NEXT** at the message and repeat the applicable steps detailed above.

This feature is active only in the random access mode of operation. The feature only appears after a run is aborted and only if that run is followed by a random access run.

21. The observed data and the calculated curve print at the end of the run. Do not press **STOP** before the printout is complete. Doing so terminates processing and prevents storage of the calibration curve. When the calibration is complete, the instrument displays:

DONE - REMOVE RPAK



### Clean-Up

22. If the wedge reagent pack is not to be used **immediately**, it should be removed from the reagent carousel. Recap the wedge reagent pack by matching the snap cap with the same wedge reagent pack from which it was removed. Remove the wedge reagent pack by pushing forward and lifting straight up. Do not remove the wedge reagent pack by lifting straight up; this will cause the tab on the front to break, and the wedge is then unusable. Return to proper storage as described on the label
23. Remove the calibration carousel and examine the sample cartridges for evidence of splashing or foaming.

**CAUTION: If splashing or foaming is observed, do not report results. These symptoms indicate a problem and require corrective action. Refer to **Section 6.0** under Observed Problems.**

24. If no splashing or foaming is observed, discard the contents of the sample carousel. All waste should be disposed of as suitable for patient samples. Refer to **decontamination** and **spill clean-up** in Section 1.0 under Operational Precautions and Limitations.
25. If separation of plastic and glass is not required, unlock the carousel, invert over a receptacle and discard the cartridges and cuvettes all at once. Ensure all sample cartridges and cuvettes have been removed.
26. If separation of glass and plastic is required, place your fingers inside the bottom of the carousel under the locking mechanism knob. Invert the carousel over a receptacle and discard the sample cartridges. Unlock the carousel, invert over a receptacle and discard the cuvettes. Ensure all sample cartridges and cuvettes have been removed.
27. Verify the calibration acceptability.

### Calibration Acceptability Criteria (Operator)

The operator verifies acceptability of a calibration curve by three criteria:

1. The PERR (polarization error) values must be within the acceptable range indicated in the assay manual insert.
2. The RMSE (root mean squared error) must be within the acceptable range indicated in the assay manual insert.
3. Each level of control must be within the acceptable ranges indicated in the assay manual insert.

If any of these values are out of range, determine the cause and recalibrate, if necessary. Refer to **Section 6.0 Observed Problems** under Calibration Fails to Meet Specification.

Reading a Therapeutic Drug Random Access Calibration Printout

**TDXFLX REAGENT CAROUSEL LOADLIST**			
RGT			EXP
LOC	REAGENT	RGT LOT#	DATE
H	PHENYTOIN		
	CAL DATE: XX/XX/XX		
TDXFLX RUN: CALIBRATION			
DATE:			
TIME:			
SERIAL #:			
LOCK=	0		
ASSAY:	PHENYTOIN		
CALIBRATION			
VOL=	1.00		
REPS=	2		
GAIN=	20		
CONC=	UG/ML		
I.D.	NET	NET	BLANK
	P	I	I
1 A	263.18	5940.0	209.4
2 A	264.23	6049.5	203.7
3 B	239.89	6120.8	205.8
4 B	238.76	6154.2	210.5
5 C	216.69	6385.3	209.4
6 C	214.96	6316.4	209.1
7 D	184.92	6626.4	206.2
8 D	185.09	6647.5	204.4
9 E	152.02	7055.8	204.8
10 E	153.24	6982.7	204.1
11 F	120.59	7495.9	201.5
12 F	120.96	7500.4	203.7
I.D.	CONC	AVGP	FITP
A	0.00	263.71	263.7
B	2.50	239.33	238.06
C	5.00	215.83	216.62
D	10.00	185.01	185.90
E	20.00	152.63	151.27
F	40.00	120.78	121.33
RMSE=	0.80		
LOC	CONC	NET P	BLK I
13	7.62	198.87	205.16
14	14.85	166.07	205.16
15	30.23	135.02	207.16
16	14.81	166.18	207.60
17	10.25	186.11	208.25
18	18.10	162.32	211.14
TESTS USED PER WEDGE			
RGTA=	RGTB=	RGTC=	RGTD=
RGTE=	RGTF=	RGTG=	RGTH=XXX

- A. List of the reagent loaded on the reagent carousel
- B. Reagent location
- C. Assay name
- D. Reagent lot number
- E. Expiration date of reagent pack
- F. Date of the last calibration performed
- G. Date of calibration
- H. Time of calibration
- I. Serial number of instrument
- J. Door lock status (0 = off, 1 = on)
- K. Reagent being calibrated
- L. Volume - final amount of calibrator in cuvette
- M. Number of calibrator replicated
- N. Gain
- O. Concentration units
- P. Position of calibrators in carousel
- Q. Net polarization - polarization of sample corrected for background reading
- R. Net intensity - fluorescence intensity readings after tracer has been added and correction for background readings made
- S. Blank intensity - calibrator background intensity reading
- T. Expected concentrations of calibrators
- U. Average polarization - the average of the net polarizations calculated for each replicated calibrator
- V. Fit polarization - the polarization values obtained when the calibration curve is fitted as close as possible to the average polarizations calculated
- W. Polarization error - calculated as the average polarization (AVGP) for each calibrator minus the fit polarization (FITP) for each calibrator
- X. Root Mean Square Error - a measurement of standard deviation of the PERRs
- Y. Concentrations, net polarizations, and blank intensity readings of the control samples
- Z. Number of tests used to date per wedge reagent pack (System 6.12 = 0)

## Assay Procedure

The following paragraphs present the step-by-step procedure for performing a random access assay run.

### System Set-Up

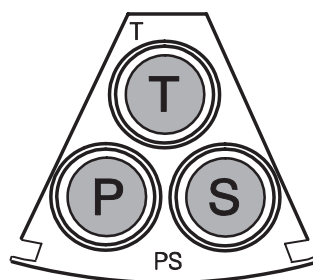
- Ensure that a random access calibration curve is stored for each assay to be run.
- Ensure that the **batch-pack adapter** has been removed.
- Ensure that all maintenance has been performed if this is the first run of the shift. Refer to **Section 5.0** for maintenance procedures.
- Program parameter options as desired. Refer to **Programmable Options** in the **Introduction** section for details.

### Preparing the Sample Carousel

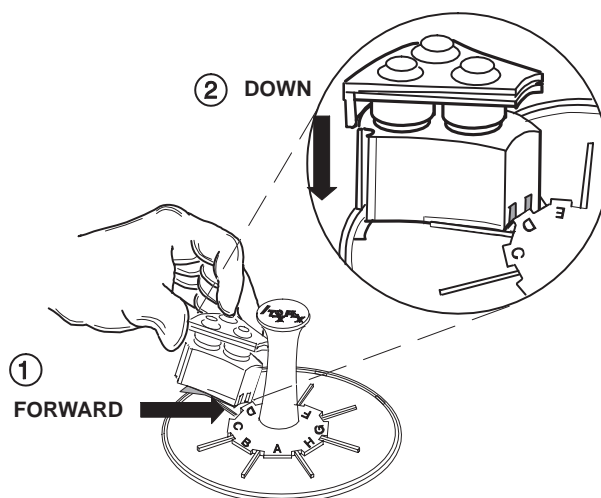
1. Select a sample carousel.
2. Load a sample cartridge and cuvette for each sample to be assayed. Begin with Position 1 and continue sequentially. Do not skip a position.
  - a. Ensure that all cuvettes are right side up.
  - b. Ensure that all disposables are clean and free of foreign matter before use.
3. Lock cuvettes into position by turning the locking mechanism clockwise until it clicks.
4. Pipette a minimum of 50  $\mu\text{L}$  (for most assays) of patient sample into sample wells for each position being used. Refer to the assays manual for specific sample volume. Avoid splashing, foaming, or bubbling.
5. Inspect the sample wells for bubbles. Remove any bubbles with applicator sticks. Use a different applicator stick for each sample.

### Preparing the Reagent Carousel

6. Select the appropriate wedge reagent pack. Verify that the S, T, and P vials are in the correct location.



7. Snap the wedge reagent packs onto the reagent carousel. It is not necessary to position the reagent packs sequentially. To insert:

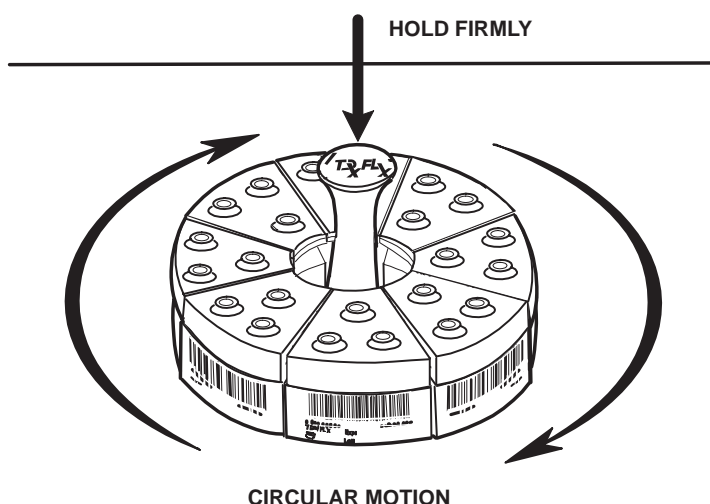


- a. Push the foot at the narrow end of the wedge under the letter tab on the carousel.
- b. Press the wide end of the wedge down firmly until it is even with the edge of the carousel rim.
- c. When positioned correctly, the wedge cannot be removed from the carousel by lifting straight up.

Place only the wedge reagent pack to be used for the assay run on the carousel.

8. Mix by swirling. Place the reagent carousel onto a level surface. Hold the carousel firmly and swirl by moving in a circular motion for at least five seconds. **Do not invert.**

**CAUTION:** Inversion of the wedge reagent pack(s) may cause liquid entrapment in the snap cap.



9. Remove and discard the vial caps after the initial use of the wedge reagent pack. Following the initial use, seal vials with the snap cap provided with the wedge reagent pack. Place snap caps upside down on a storage container or surface after they are removed.

**CAUTION:** Reagent packs not being used for the immediate run must be removed, recapped and returned to proper storage conditions.

10. Inspect the vials for bubbles. Remove any bubbles with applicator sticks. Use a different applicator stick for each vial.

### Run Assay

11. Insert the reagent carousel into the analyzer.
12. Place the loaded sample carousel into the instrument. Close the carousel access door.
13. Press **RUN**.
14. If the instrument is not programmed to record operator ID (**System 6.3** = 0), go to Step 15. If it is programmed to record this number, the display reads:

OP ID?

Enter the ID number using the barcode scanner or the numerical keypad for this input. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

15. Steps 16 and 17 are activated under specific circumstances. In most cases, these two steps are skipped by the instrument. If they are skipped, proceed directly to **Step 18**. If not, then perform these steps; the instrument prompts for the necessary input.
16. If the boom-arm barcode reader fails to detect the sample carousel barcode label properly, the instrument must be programmed for the type of run to perform. In this instance, the display reads:

CALIBRATION?

Press **NEXT** and continue with Step 17.

17. If the instrument detects a new/unused wedge reagent pack, the display reads:

RGT # ? \_ \_ \_ \_ \_

Enter the corresponding lot number of the wedge reagent pack and press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number. Repeat this step for all occurrences.

The lot number prompt is only activated the first time a new/unused wedge reagent pack is detected. The instrument skips this step after a wedge reagent pack is initialized into the system.

18. If the instrument is not programmed to record the reagent loadlist (**System 6.13** = 0), go to Step 19. If the instrument is programmed to record this information, a list of the reagents loaded on the reagent carousel is printed. Corresponding assay names and the number of tests used (or tests left) on that wedge reagent pack are also displayed on the reagent display. The display reads:

REAGENT LIST OK?

If the reagent list is correct, press **STORE** and proceed to Step 19.

If the reagent list is incorrect, press **NEXT**. If there were unsuccessful reads (caused by barcode fail or empty position on the reagent carousel), the carousel rotates and positions the first wedge reagent pack that had an unsuccessful read at the 5 o'clock position. This position is indicated by an arrow on the baseplate.

At this point the system enters barcode override. Repeat this step for each unsuccessful read.

Refer to the **barcode-override procedures** for additional information.

If the loadlist must be edited in order to replace a wedge reagent pack, press **STOP**. Then remove the carousel, make the necessary changes, and begin the run sequence again.

**CAUTION: Do not remove the reagent carousel without first pressing the STOP key.**

19. If only one wedge reagent pack is being tested the instrument will automatically proceed to **Step 20**. If more than one wedge reagent pack is being tested, the display reads:

ENTER SAMPLE LST

followed by

LOC 1 ASSAY # \_ \_

Enter the assay number for Location 1 by pressing its corresponding assay key on the reagent keypad. The assay number can also be entered through the numerical keypad. Press **STORE** after each entry.

20. If the instrument is not programmed to record the patient ID number (**System 6.6** = 0), go to Step 21. If the instrument is programmed to record the patient ID number, the display reads:

ID 1?

Enter the patient ID number by using either the barcode scanner or the numerical keypad. Controls may be identified by scanning the TDxFLx<sup>®</sup> QC Barcode label. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

21. The display reads:

LOC 2 ASSAY # \_ \_

22. Repeat **Steps 19** and 20 until all samples on the carousel are entered.
23. Ensure that the carousel access door is closed, and press **RUN**. If the instrument is not programmed to prompt for the sample loadlist (**System 6.14** = 0), go to Step 24. If it is programmed to record this information, the sample loadlist prints and the display reads:

ASSAY LIST OK?

Press **STORE/YES** if the list is correct, and proceed to the next step.

Press **NEXT/NO** if the list is incorrect. The display updates with:

LOC 1 ASSAY # \_ \_

Press **NEXT** to scroll forward or **EDIT** to scroll backward through the sample carousel locations and patient ID numbers until the incorrect entry is reached.

24. Once the list is corrected, repeat Step 23.

**NOTES:** After entering a valid reagent loadlist and a sample loadlist, the instrument stores the lists temporarily. If the run is aborted, the display reads [SAME RGT CRSL?] and [SAME SAMPLE LST?] when restarting the run.

If the configurations of the reagent carousel and the sample carousel remain the same, press **STORE** for both messages to accept the lists.

If the configuration is different, press **NEXT** for both messages and repeat the applicable steps detailed above.

This feature is active only in the random access mode of operation. The feature only appears after a run is aborted and only if that run is followed by a random access run.



25. Wait for an entire printout. The run is complete when the display reads:

DONE - REMOVE RPAK

### Clean-Up

26. If the wedge reagent pack is not to be used **immediately**, it should be removed from the reagent carousel. Recap the wedge reagent packs by matching the snap cap with the same wedge reagent pack from which it was removed. Remove the wedge reagent pack by pushing forward and lifting straight up. Do not remove the wedge reagent pack by lifting straight up; this will cause the tab on the front to break, and the wedge is then unusable. Return to proper storage as described on the label.
27. Remove the sample carousel and examine the sample cartridges for evidence of splashing or foaming.

**CAUTION:** If splashing or foaming is observed, do not report results. These symptoms indicate a problem and require corrective action. Refer to the **Section 6.0** under Observed Problems.

28. If no splashing or foaming is observed, discard the contents of the sample carousel. All waste should be disposed of as suitable for patient samples. Refer to **decontamination** and **spill clean-up** in Section 1.0 under Operational Precautions and Limitations.
29. If separation of plastic and glass is not required, unlock the carousel, invert over a receptacle and discard the cartridges and cuvettes all at once. Ensure that all sample cartridges and cuvettes have been removed.
30. If separation of glass and plastic is required, place your fingers inside the bottom of the carousel under the locking mechanism knob. Invert the carousel over a receptacle and discard the sample cartridges. Unlock the carousel, invert over a receptacle and discard the cuvettes. Ensure that all sample cartridges and cuvettes are removed.

Reading a Therapeutic Drug Random Access Assay Printout (System 6.10 Collate = 0)

A

\*\*TDXFLX REAGENT CAROUSEL LOADLIST\*\*

B

LOC

C

REAGENT

D

RGT LOT#

E

EXP DATE

A

GENTAMICIN

F

CAL DATE:

B

TOBRAMYCIN

CAL DATE:

C

AMIKACIN

CAL DATE:

TDXFLX RUN

DATE:

G

TIME:

H

SERIAL #:

I

LOCK= 1

J

OP ID:

K

CAROUSEL: 3

L

SAMPLE LOADLIST

M

N

LOC

O

ASSAY

PATIENT ID

1

GENTAMICIN

1234567891

2

TOBRAMYCIN

2222222220

3

AMIKACIN

3339845001

LOC

ASSAY

PATIENT ID

CONC

1

GENT

1234567891

0.99 UG/ML

P

NET P:

175.10

Q

BLK I:

72.09

2

TOBRA

2222222220

0.98 UG/ML

NET P:

155.96

BLK I:

125.94

3

AMIK

3339845001

4.79 UG/ML

NET P:

201.63

BLK I:

122.44

S

TESTS USED PER WEDGE

RGTA=XXX RGTB=XXX RGTC=XXX RGTD=

RGTE= RGTF= RGTG= RGTH=

- A. List of the reagents loaded on the reagent carousel (optional feature)
- B. Reagent location
- C. Assay name
- D. Reagent lot number of each reagent
- E. Expiration date of each reagent pack
- F. Date of the last calibration
- G. Date of assay run
- H. Time of assay run
- I. Serial number of instrument
- J. Door lock status (0 = off, 1 = on)
- K. Operator ID number (optional feature)
- L. Sample carousel number
- M. Sample loadlist (optional feature)
- N. Assay being performed on sample in Position 1
- O. Patient ID number (optional feature)
- P. Net polarization - polarization of sample corrected for background reading
- Q. Blank intensity - serum background intensity reading
- R. Concentration units
- S. Number of tests used to date per wedge reagent pack (System 6.12 = 0)

### HI and LOW Readings

The following is a description of the HI and LO flags that can appear on the printout. More detailed information concerning these flags can be found in [Section 6.0 Troubleshooting](#).

#### **HI or LOW Printed After CONC Result**

- If any result is outside of the programmed therapeutic range (assay parameters .3 and .4), the patient result is flagged as HI or LOW. This alerts the operator to an out-of-range sample. The results should be given special attention and the responsible personnel notified per laboratory procedure.

#### **HI or LOW Printed Instead of CONC Result**

- If the Net P value is outside the span of the calibration curve, a HI or LOW prints instead of the numeric result.
- If LOW prints, see [Section 6.0 Troubleshooting](#) before proceeding further.
- If LOW is repeated after following all troubleshooting steps, the concentration may be reported as less than the sensitivity of the specific assay. The sensitivity is provided in the assay manual insert.
- If HI prints, the test should be rerun using Dilution Protocol. Refer to the [Dilution Protocol](#) procedure in this section.

**Panel Testing Overview**

A panel is a group of assays run on the same aliquot of sample.

Nine unique panels with a maximum of eight assays per panel can be programmed.

**Panel Procedure****Selecting Assay Combinations**

A panel can include:

- any random access assay
- assay replicates

**NOTE:** Concentration averages are not calculated for replicate assays in a panel.

A panel cannot include:

- assays not available in the random access mode
- assay combinations using different sample matrices

**Selecting Panel/Assay Combinations for a Run**

A run can include any combination and sequence of single tests and panels.

### Programming

- Nine unique panels with a maximum of eight assays per panel can be programmed. Panel numbers 1 - 9 and assay locations 1 - 8 are accepted by the system.
- Do not skip assay locations within a panel. If a location is skipped, assays following the skipped panel location are not identified by the system.
- During operation, assay locations assigned to a panel are independent of reagent pack positions on the reagent carousel.

#### 1. Press **SYSTEM 11**. (panel number) **EDIT**.

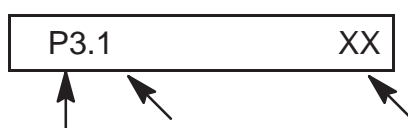
[PANEL (panel number)] displays.

#### 2. Press **NEXT**. The display reads:

[P (panel number) . (assay location)                      XX]

XX represents the assay number. If an assay number is not programmed for the assay location, XX equals zero.

For example:



**PANEL 3    ASSAY LOCATION 1    ASSAY NUMBER**

3. Enter the assay number to edit/add an assay, or press **CLEAR** to delete an assay.
4. Press **STORE**.
5. Press **NEXT** to proceed to the next assay location on the panel. The display reads:  
[P (panel number) . (next assay location)                      XX]
6. Enter assay numbers for the remaining assay locations of the panel as appropriate. Do not skip any assay locations within a panel.
7. Press **STOP** to return to [READY].  
If the **NEXT** key is pressed when the assay location = 8, the system displays the next panel number.
8. Proceed to **Step 9** to print a panel report.

Printing

9. Press **TEST 6.9 RUN**.

The display alternates between [PANEL REPORT] and the programmed assay names.

The system prints a listing of panel locations, assay names, and assay numbers for all panels.

[DONE] displays at the completion of the routine.

10. Press **STOP** to return to [READY].

END OF REPORT appears at the end of the printout.

11. Verify that the panel information on the printout is correct, and retain the printout for future reference.

PANEL LOCATION		ASSAY NAME	ASSAY NUMBER
PANEL REPORT			
11.1	PANEL 1		
11.1.1	P1.1	PROCAINAMIDE	12
11.1.2	P1.2	NAPA	13
11.1.3	P1.3		
11.1.4.	P1.4		
11.1.5	P1.5		
11.1.6	P1.6		
11.1.7	P1.7		
11.1.8	P1.8		
11.2	PANEL 2		
11.2.1	P2.1	PHENYTOIN	4
11.2.2	P2.2	PHENOBARBITAL	5
11.2.3	P2.3		
11.2.4	P2.4		
11.2.5	P2.5		
11.2.6	P2.6		
11.2.7	P2.7		
11.2.8	P2.8		
11.3	PANEL 3		
etc.			

Sample Panel Report Printout

System Set-Up

- Ensure that a random access calibration curve is stored for each assay to be run.
- Ensure that the batch-pack adapter has been removed.
- Ensure panels are programmed for the assays that will be run.
- Ensure that all maintenance has been performed if this is the first run of the shift. Refer to Section 5.0 for maintenance procedures.
- Program parameter options as desired. Refer to Programmable Options in the Introduction Section for details.

Preparing the Sample Carousel

1. Select a sample carousel.
2. Load a sample cartridge and cuvette for each sample to be assayed. Begin with Position 1 and continue sequentially. Do not skip a position.
  - a. Ensure that all cuvettes are right side up.
  - b. Ensure that all disposables are clean and free of foreign matter before use.
3. Lock cuvettes into position by turning the locking mechanism clockwise until it clicks.
4. Pipette sample into only the first position of a panel. Avoid splashing, foaming, or bubbling.

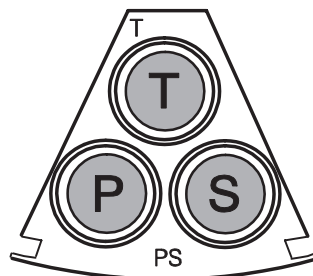
Pipette enough sample to accommodate all tests defined for a panel into the first sample cartridge position of the panel. The analyzer transfers sample to the remaining positions of the panel during operation. Use the following table to determine the range of acceptable sample volumes for different numbers of tests per panel.

Sample Volumes for Panel Testing		
Number of Tests per Panel	Minimum Sample Volume (µL)	Maximum Sample Volume (µL)
2	140	500
3	200	500
4	260	500
5	320	500
6	380	500
7	440	500
8	500	500

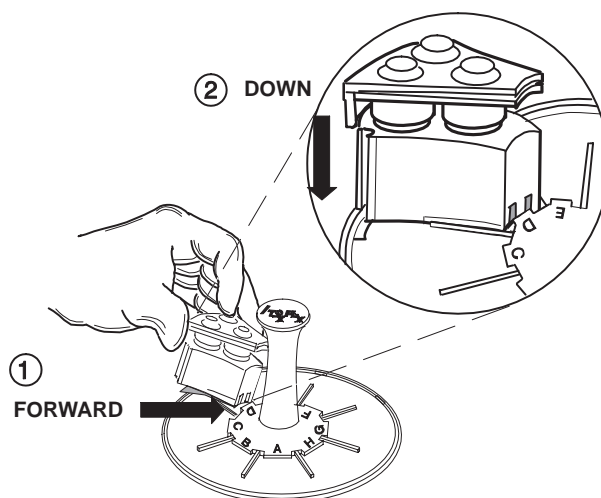
5. Inspect the sample wells for wells for bubbles. Remove any bubbles with applicator sticks. Use a different applicator stick for each sample.

### Preparing the Reagent Carousel

6. Select the appropriate wedge reagent pack. Verify that the S, T, and P vials are in the correct location.



7. Snap the wedge reagent pack onto the reagent carousel. The reagent carousel barcode reader identifies the location of the wedge reagent packs during operation. It is not necessary to position the reagent packs sequentially. To insert:



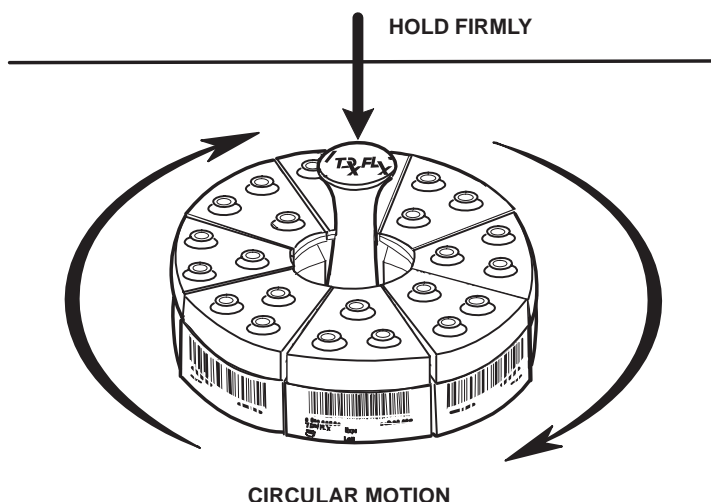
- a. Push the foot at the narrow end of the wedge under the letter tab on the carousel.
- b. Press the wide end of the wedge down firmly until it is even with the edge of the carousel rim.
- c. When positioned correctly, the wedge cannot be removed from the carousel by lifting straight up.

Place only the wedge reagent pack to be used for the assay run on the carousel.



8. Mix by swirling. Place the reagent carousel onto a level surface. Hold the carousel firmly and swirl by moving in a circular motion for at least five seconds. **Do not invert.**

**CAUTION:** Inversion of the wedge reagent pack(s) may cause liquid entrapment in the snap cap.



9. Remove and discard the vial caps after the initial use of the wedge reagent pack. Following the initial use, seal vials with the snap cap provided with the wedge reagent pack. Place snap caps upside down on a storage container or surface after they are removed.

**CAUTION:** Reagent packs not being used for the immediate run must be removed, recapped and returned to proper storage conditions.

10. Inspect the vials for bubbles. Remove any bubbles with applicator sticks. Use a different applicator stick for each vial.

### Run Panel

11. Insert the reagent carousel into the analyzer.
12. Place the loaded sample carousel into the instrument. Close the carousel access door.
13. Press **RUN**.
14. If the instrument is not programmed to record operator ID (**System 6.3** = 0), go to Step 15. If it is programmed to record this number, the display reads:

OP ID?

Enter the ID number using the barcode scanner or the numerical keypad for this input. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

15. Steps 16 and 17 are activated under specific circumstances. In most cases, these two steps are skipped by the instrument. If they are skipped, proceed directly to **Step 18**. If not, then perform these steps; the instrument prompts for the necessary input.
16. If the boom-arm barcode reader fails to detect the sample carousel barcode label properly, the instrument must be programmed for the type of run to perform. In this instance, the display reads:

CALIBRATION?

Press **NEXT** and continue with Step 17.

17. If the instrument detects a new/unused wedge reagent pack, the display reads:

RGT # ? \_ \_ \_ \_ \_

Enter the corresponding lot number of the wedge reagent pack and press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number. Repeat this step for all occurrences.

The lot number prompt is only activated the first time a new/unused wedge reagent pack is detected. The instrument skips this step after a wedge reagent pack is initialized into the system.

18. If the instrument is not programmed to record the reagent loadlist (**System 6.13** = 0), go to Step 19. If the instrument is programmed to record this information, a list of the reagents loaded on the reagent carousel is printed. Corresponding assay names and the number of tests used (or tests left) on that wedge reagent pack are also displayed on the reagent display. The display reads:

REAGENT LIST OK?

If the reagent list is correct, press **STORE** and proceed to Step 19.

If the reagent list is incorrect, press **NEXT**. If there were unsuccessful reads (caused by barcode fail or empty position on the reagent carousel), the carousel rotates and positions the first wedge reagent pack that had an unsuccessful read at the 5 o'clock position. This position is indicated by an arrow on the baseplate.

At this point the system enters barcode override. Repeat this step for each unsuccessful read.

Refer to the **barcode-override procedures** for additional information.

If the loadlist must be edited in order to replace a wedge reagent pack, press **STOP**. Then remove the carousel, make the necessary changes, and begin the run sequence again.

**CAUTION:** Do not remove the reagent carousel without first pressing the **STOP** key.

19. If only one wedge reagent pack is being tested the instrument will automatically proceed to **Step 22**. If the instrument is not programmed to prompt for the sample loadlist (**System 6.14** = 0), go to **Step 20**. If it is programmed to record this information, the display reads:

ENTER SAMPLE LST

followed by

LOC 1 ASSAY # \_ \_

20. If a single test is desired for Location 1, press the assay key on the reagent keypad. Proceed to Step 22.

If a panel of tests is desired for Location 1, proceed to Step 21.

21. Press the \* (PANEL) key on the reagent keypad. The display reads:

LOC 1 PANEL # \_

Select the panel desired.

- Enter the appropriate panel number (1 - 9) to select a programmed panel  
or
- Enter **0** to select a panel consisting of the assays matching the wedge reagent packs loaded on the reagent carousel.

Press **STORE** after each entry.

22. If the instrument is not programmed to record the patient ID number (**System 6.6** = 0), go to Step 23. If the instrument is programmed to record the patient ID number, the display reads:

ID 1?

Enter the patient ID number by using either the barcode scanner or the numerical keypad. Controls may be identified by scanning the TDxFLx<sup>®</sup> QC Barcode label. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

23. If a single test was defined for Location 1, the display reads:

LOC 2 ASSAY # \_ \_

If a panel of tests were defined for Location 1, the display skips to the next available sample location. For example, if a panel containing three assays was defined for Location 1, the display reads:

LOC 4 ASSAY # \_ \_

24. Repeat Steps 20 - 23 until all samples on the carousel are entered.

25. Ensure that the carousel access door is closed, and press **RUN**. If the instrument is not programmed to prompt for the sample loadlist (**System 6.14** = 0), go to Step 27. If it is programmed to record this information, the sample loadlist prints and the display reads:

ASSAY LIST OK?

Press **STORE/YES** if the list is correct, and proceed to the next step.

Press **NEXT/NO** if the list is incorrect. The display updates with:

LOC 1 ASSAY # \_ \_

Press **NEXT** to scroll forward or **EDIT** to scroll backward through the sample carousel locations until the incorrect entry is reached.

26. Once the list has been corrected, repeat Step 25.

**NOTES:** After entering a valid reagent loadlist and a sample loadlist, the instrument stores the lists temporarily. If the run is aborted, the display reads [SAME RGT CRSL?] and [SAME SAMPLE LST?] when restarting the run.

If the configurations of the reagent carousel and the sample carousel remain the same, press **STORE** for both messages to accept the lists.

If the configuration is different, press **NEXT** for both messages and repeat the applicable steps detailed above.

This feature is active only in the random access mode of operation. The feature only appears after a run is aborted and only if that run is followed by a random access run.

27. Wait for an entire printout. The run is complete when the display reads:

DONE - REMOVE RPAK

### Clean-Up

28. If the wedge reagent pack is not to be used **immediately**, it should be removed from the reagent carousel. Recap the wedge reagent packs by matching the snap cap with the same wedge reagent pack from which it was removed. Remove the wedge reagent pack by pushing forward and lifting straight up. Do not remove the wedge reagent pack by lifting straight up; this will cause the tab on the front to break, and the wedge is then unusable. Return to proper storage as described on the label
29. Remove the sample carousel and examine the sample cartridges for evidence of splashing or foaming.

**CAUTION: If splashing or foaming is observed, do not report results. These symptoms indicate a problem and require corrective action. Refer to the **Section 6.0** under Observed Problems.**

30. If no splashing or foaming is observed, discard the contents of the sample carousel. All waste should be disposed of as suitable for patient samples. Refer to **decontamination** and **spill clean-up** in Section 1.0 under Operational Precautions and Limitations.
31. If separation of plastic and glass is not required, unlock the carousel, invert over a receptacle and discard the cartridges and cuvettes all at once. Ensure that all sample cartridges and cuvettes have been removed.
32. If separation of glass and plastic is required, place your fingers inside the bottom of the carousel under the locking mechanism knob. Invert the carousel over a receptacle and discard the sample cartridges. Unlock the carousel, invert over a receptacle and discard the cuvettes. Ensure that all sample cartridges and cuvettes are removed.

Reading a Panel Test Printout (System 6.10 Collate = 0)

A

\*\*TDXFLX REAGENT CAROUSEL LOADLIST\*\*

B

RGT

LOC

C

REAGENT

D

RGT LOT#

E

EXP DATE

A

PHENYTOIN

F

CAL DATE:

B

PHENOBARBITAL

CAL DATE:

TDXFLX RUN

DATE: G

TIME: H

SERIAL #: I

LOCK= 0 J

OP ID: K

CAROUSEL: L

SAMPLE LOADLIST M

N

LOC

ASSAY

PATIENT ID

1

PHENYTOIN

1234567891

2

PHENOBARBITAL

1234567891

3

PHENYTOIN

1987654321

4

PHENOBARBITAL

1987654321

LOC

ASSAY

PATIENT ID

CONC

1

PHENY

1234567891

0.44 UG/ML

P

NET P:

Q

BLK I:

2

PHNOB

1234567891

0.21 UG/ML

NET P:

BLK I:

3

PHENY

1987654321

0.36 UG/ML

NET P:

BLK I:

4

PHNOB

1987654321

LOW UG/ML

NET P:

BLK I:

S

TESTS LEFT PER WEDGE

RGTA=XXX RGTB=XXX RGTC=

RGTD=

RGTE=

RGTF=

RGTG=

RGTH=

- A. List of the reagents loaded on the reagent carousel (optional feature)
- B. Reagent location
- C. Assay name
- D. Reagent lot number of each reagent
- E. Expiration date of each reagent pack
- F. Date of last calibration
- G. Date of assay run
- H. Time of assay run
- I. Serial number of instrument
- J. Door lock status (0 = off, 1 = on)
- K. Operator ID number (optional feature)
- L. Sample carousel number
- M. Sample loadlist (optional feature)
- N. Location of assays
- O. Patient ID (optional feature)
- P. Net polarization - polarization of sample corrected for background reading
- Q. Blank intensity - serum background intensity reading
- R. Concentration units
- S. Number of tests left per wedge reagent pack (System 6.12 = 1)

### Printout Options

Random access test results can be printed using one of three printout options. The following printouts illustrate how these different printout options will appear. Refer to **Programmable Options** in the Introduction section, under **System 6.10 Printout Format**, for instructions on how to use this feature.



Sample Printout with Collate Option (System 6.10) Set to 0

When System 6.10 = 0, the instrument collates results by the sample loadlist location.

**TDXFLX REAGENT CAROUSEL LOADLIST**				
RGT				EXP
LOC	REAGENT	RGT LOT#		DATE
A	PHENOBARBITAL			
	CAL DATE: XX/XX/XX			
C	AMIKACIN			
	CAL DATE: XX/XX/XX			
D	GENTAMICIN			
	CAL DATE: XX/XX/XX			
H	TOBRAMYCIN			
	CAL DATE: XX/XX/XX			
TDXFLX RUN				
DATE:				
TIME:				
SERIAL #: 60022				
LOCK= 1				
OP ID: 5187335				
CAROUSEL: 1				
SAMPLE LOADLIST				
LOC	ASSAY	PATIENT ID		
1	PHENOBARBITAL	04648		
2	GENTAMICIN	04651		
3	AMIKACIN	04647		
4	PHENOBARBITAL	04652		
5	TOBRAMYCIN	04651		
LOC	ASSAY	PATIENT ID	CONC	
1	PHNOB	04648	3.10	UG/ML
	NET P:	191.70		
	BLK I:	109.53		
2	GENT	04651	0.99	UG/ML
	NET P:	175.10		
	BLK I:	72.09		
3	AMIK	04647	4.79	UG/ML
	NET P:	201.63		
	BLK I:	122.44		
4	PHNOB	04652	3.03	UG/ML
	NET P:	192.01		
	BLK I:	109.54		
5	TOBRA	04651	0.98	UG/ML
	NET P:	155.96		
	BLK I:	125.94		
TESTS LEFT PER WEDGE				
RGTA=XXX	RGTB=	RGTC=XXX	RGTD=XXX	
RGTE=	RGTF=	RGTG=	RGTH=XXX	

Sample Printout with Collate Option (System 6.10) Set to 1

**TDXFLX REAGENT CAROUSEL LOADLIST**			
RGT			EXP
<u>LOC</u>	<u>REAGENT</u>	<u>RGT LOT#</u>	<u>DATE</u>
A	PHENOBARBITAL		
	CAL DATE: XX/XX/XX		
C	AMIKACIN		
	CAL DATE: XX/XX/XX		
D	GENTAMICIN		
	CAL DATE: XX/XX/XX		
H	TOBRAMYCIN		
	CAL DATE: XX/XX/XX		
TDXFLX RUN			
DATE:			
TIME:			
SERIAL #: 60022			
LOCK= 1			
OP ID: 5187335			
CAROUSEL: 1			
SAMPLE LOADLIST			
<u>LOC</u>	<u>ASSAY</u>	<u>PATIENT ID</u>	
1	PHENOBARBITAL	04648	
2	GENTAMICIN	04651	
3	AMIKACIN	04647	
4	PHENOBARBITAL	04652	
5	TOBRAMYCIN	04651	
PATIENT-ID FORMAT			
<u>RESULTS GROUPED BY PATIENT-ID</u>			
<u>LOC</u>	<u>ASSAY</u>	<u>PATIENT ID</u>	<u>CONC</u>
1	PHNOB	04648	3.10 UG/ML
	NET P:	191.70	
	BLK I:	109.53	
2	GENT	04651	0.99 UG/ML
	NET P:	175.10	
	BLK I:	72.09	
5	TOBRA	04651	0.98 UG/ML
	NET P:	155.96	
	BLK I:	125.94	
3	AMIK	04647	4.79 UG/ML
	NET P:	201.63	
	BLK I:	122.44	
4	PHNOB	04652	3.03 UG/ML
	NET P:	192.01	
	BLK I:	109.54	
TESTS LEFT PER WEDGE			
RGTA=XXX	RGTB=	RGTC=XXX	RGTD=XXX
RGTE=	RGTF=	RGTG=	RGTH=XXX

When System 6.10 = 1, the instrument collates results by patient ID. If multiple tests are run on the same patient, results are grouped and printed consecutively as the patient ID appears on the sample loadlist.

Sample Printout with Collate Option (System 6.10) Set to 2

**TDXFLX REAGENT CAROUSEL LOADLIST**			
RGT			EXP
<u>LOC</u>	<u>REAGENT</u>	<u>RGT LOT#</u>	<u>DATE</u>
A	PHENOBARBITAL		
	CAL DATE: XX/XX/XX		
C	AMIKACIN		
	CAL DATE: XX/XX/XX		
D	GENTAMICIN		
	CAL DATE: XX/XX/XX		
H	TOBRAMYCIN		
	CAL DATE: XX/XX/XX		
TDXFLX RUN			
DATE:			
TIME:			
SERIAL #: 60022			
LOCK= 1			
OP ID: 5187335			
CAROUSEL: 1			
SAMPLE LOADLIST			
<u>LOC</u>	<u>ASSAY</u>	<u>PATIENT ID</u>	
1	PHENOBARBITAL	04648	
2	GENTAMICIN	04651	
3	AMIKACIN	04647	
4	PHENOBARBITAL	04652	
5	TOBRAMYCIN	04651	
ASSAY FORMAT			
<u>RESULTS GROUPED BY ASSAY</u>			
<u>LOC</u>	<u>ASSAY</u>	<u>PATIENT ID</u>	<u>CONC</u>
1	PHNOB	04648	3.10
	NET P:	191.70	
	BLK I:	109.53	
			UG/ML
4	PHNOB	04652	3.03
	NET P:	192.01	
	BLK I:	109.54	
			UG/ML
2	GENT	04651	0.99
	NET P:	175.10	
	BLK I:	72.09	
			UG/ML
3	AMIK	04647	4.79
	NET P:	201.63	
	BLK I:	122.44	
			UG/ML
5	TOBRA	04651	0.98
	NET P:	155.96	
	BLK I:	125.94	
			UG/ML
TESTS LEFT PER WEDGE			
RGTA=XXX	RGTB=	RGTC=XXX	RGTD=XXX
RGTE=	RGTF=	RGTG=	RGTH=XXX

When System 6.10 = 2, the instrument collates results by assay type. If multiple tests for the same assay are run, results are grouped and printed consecutively as the assay appears on the sample loadlist.

Barcode Override

The following paragraphs detail barcode-override procedures for random access runs.

Calibration

- 1. Press **ASSAY RUN**.
- 2. The instrument prompts

CALIBRATION?

Press **STORE** to activate the calibration procedure.

- 3. If the instrument is not programmed to record the operator ID (**System 6.3** = 0), go to Step 4. If it is programmed to record this number, the display reads:

OP ID?

Enter the ID number using the barcode scanner or the numerical keypad for this input. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

- 4. The display updates briefly with

ENTER RGT LDLIST

followed by

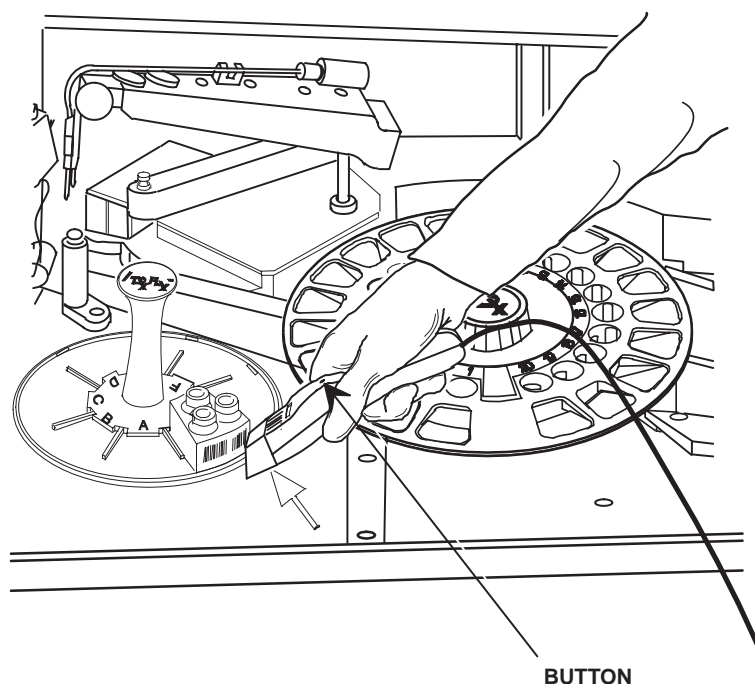
A=\_\_\_\_\_

If a wedge reagent pack is not found in Location A, press **NEXT** to skip empty location(s) until the appropriate wedge reagent pack is reached.

Ensure that the reagent carousel is not bumped or moved by pressing down firmly on the carousel handle. Enter the 13-digit reagent barcode number using the barcode scanner or the numerical keypad.

### Barcode Scanner

Scan the barcode label of the wedge reagent pack at the 5 o'clock position. This position is indicated by an arrow on the baseplate. Press the button and aim the scanner at the barcode label. Ensure the scanner light encompasses the entire barcode label of the wedge reagent pack. The scanner beeps when it recognizes the label. If the scanner does not read a label within 60 seconds, it automatically shuts off.



### Numerical Keypad

Enter the 13-digit barcode number through the numerical keypad. If an error is made, press **CLEAR**. When the number has been entered correctly, press **STORE**.

The corresponding assay name and the number of tests used or tests left on that wedge reagent pack are displayed on the reagent display.

- If the instrument detects a new/unused wedge reagent pack, the display reads:

RGT # ? \_ \_ \_ \_ \_

Enter the corresponding lot number of the wedge reagent pack and press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

The lot number prompt is only activated the first time a new/unused wedge reagent pack is detected. The instrument skips this step after a wedge reagent pack is initialized into the system.

6. Press **RUN**.
7. If the instrument is not programmed to record the reagent loadlist (**System 6.13** = 0), go to Step 8. If the instrument is programmed to record this information, a list of the reagents loaded on the reagent carousel is printed. Corresponding assay names and the number of tests used (or tests left) on that wedge reagent pack are also displayed on the reagent display. The display reads:

REAGENT LIST OK?

If the reagent list is correct, press **STORE** and proceed to Step 8. If the reagent list is incorrect, press **STOP**. Then remove the carousel, make the necessary changes, and begin the run sequence again.

**CAUTION:** Do not remove the reagent carousel without first pressing the **STOP** key.

8. Close the carousel access door. Verify that the correct assay name and the word [CALIBRATION] displays.

**NOTES:** After entering a valid reagent loadlist the instrument stores the list temporarily. If the run is aborted, the display reads [SAME RGT CRSL?] when restarting the run.

If the configuration of the reagent carousel remains the same, press **STORE** for the message to accept the list.

If the configuration is different, press **NEXT** at the message, and repeat the applicable steps detailed above.

This feature is active only in the random access mode of operation. The feature only appears after a run is aborted and only if that run is followed by random access run.

9. The observed data and the calculated curve print at the end of the run. Do not press **STOP** before the printout is complete. Doing so terminates processing and prevents storage of the calibration curve. When the calibration is complete, the instrument displays:

DONE - REMOVE RPAK

### Assay Run

1. Press **ASSAY RUN**.
2. The instrument prompts

CALIBRATION?

3. Press **NEXT**. The display reads:

CAROUSEL # ? \_ \_

Enter the sample carousel number and press **STORE**.

4. If the instrument is not programmed to record the operator ID (**System 6.3** = 0), go to Step 5. If it is programmed to record this number, the display reads:

OP ID?

Enter the ID number using the barcode scanner or the numerical keypad for this input. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

5. The display updates briefly with

ENTER RGT LDLIST

followed by

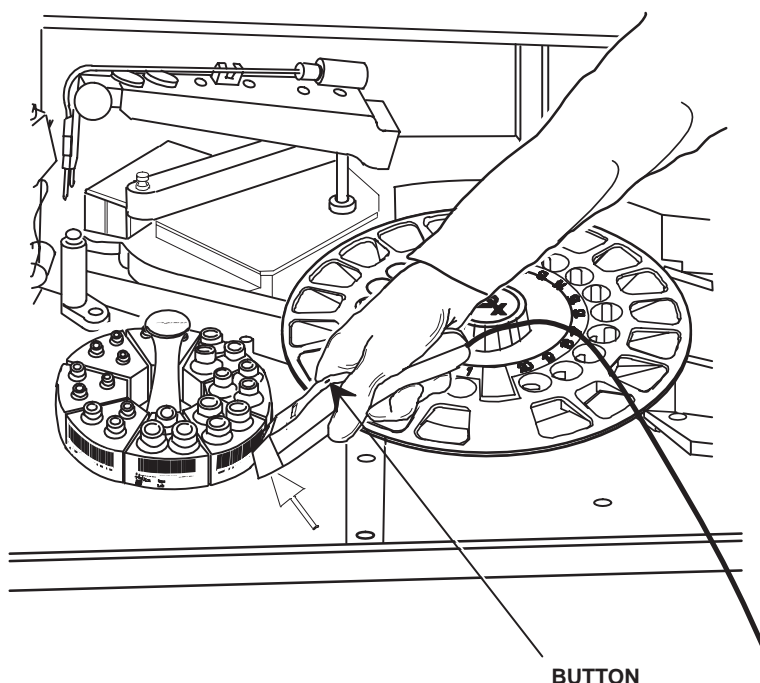
A= \_ \_ \_ \_ \_

If a wedge reagent pack is not found in Location A, press **NEXT** to skip empty location(s) until the appropriate wedge reagent pack is reached.

Ensure that the reagent carousel is not bumped or moved by pressing down firmly on the carousel handle. Enter the 13-digit reagent barcode number using the barcode scanner or the numerical keypad.

### Barcode Scanner

Scan the barcode label of the wedge reagent pack at the 5 o'clock position. This position is indicated by an arrow on the baseplate. Press the button and aim the scanner at the barcode label. Ensure the scanner light encompasses the entire barcode label of the wedge reagent pack. The scanner beeps when it recognizes the label. If the scanner does not read a label within 60 seconds, it automatically shuts off.



### Numerical Keypad

Enter the 13-digit barcode number through the numerical keypad. If an error is made, press **CLEAR**. When the number has been entered correctly, press **STORE**.

The corresponding assay name and the number of tests used or tests left on that wedge reagent pack are displayed on the reagent display.



6. If the instrument detects a new/unused wedge reagent pack, the display reads:

RGT # ? \_ \_ \_ \_ \_

Enter the corresponding lot number of the wedge reagent pack and press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number. Repeat this step for all occurrences.

The lot number prompt is only activated the first time a new/unused wedge reagent pack is detected. The instrument skips this step after a wedge reagent pack is initialized into the system.

7. Press **RUN**.
8. If the instrument is not programmed to record the reagent loadlist (**System 6.13** = 0), go to Step 9. If the instrument is programmed to record this information, a list of the reagents loaded on the reagent carousel is printed. Corresponding assay names and the number of tests used (or tests left) on that wedge reagent pack are also displayed on the reagent display. The display reads:

REAGENT LIST OK?

If the reagent list is correct, press **STORE** and proceed to Step 9. If the loadlist must be edited in order to replace a wedge reagent pack, press **STOP**. Then remove the carousel, make the necessary changes, and begin the run sequence again.

**CAUTION: Do not remove the reagent carousel without first pressing the STOP key.**

9. If only one wedge reagent pack is being tested the instrument will automatically proceed to **Step 15**. If the instrument is not programmed to prompt for the sample loadlist (**System 6.14** = 0), go to **Step 10**. If it is programmed to record this information, the display reads:

ENTER SAMPLE LST

followed by

LOC 1 ASSAY # \_ \_

10. If a single test is desired for Location 1, press the assay key on the reagent keypad. Proceed to Step 12.

If a panel of tests is desired for Location 1, proceed to Step 11.

11. Press the \* (PANEL) key on the reagent keypad. The display reads:

LOC 1 PANEL # \_

Select the panel desired.

- Enter the appropriate panel number (1 - 9) to select a programmed panel  
or
- Enter **0** to select a panel consisting of the assays matching the wedge reagent packs loaded on the reagent carousel.

Press **STORE** after each entry.

12. If the instrument is not programmed to record the patient ID number (**System 6.6** = 0), go to Step 14. If the instrument is programmed to record the patient ID number, the display reads:

ID 1?

Enter the patient ID number by using either the barcode scanner or the numerical keypad. Controls may be identified by scanning the TDxFLx<sup>®</sup> QC Barcode label. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

13. If a single test was defined for Location 1, the display reads:

LOC 2 ASSAY # \_ \_

If a panel of tests were defined for Location 1, the display skips to the next available sample location. For example, if a panel containing three assays was defined for Location 1, the display reads:

LOC 4 ASSAY # \_ \_

14. Repeat Steps 10 - 12 until all samples on the carousel are entered.

15. If only one reagent pack is loaded on the reagent carousel the instrument will prompt [CLOSE THE DOOR] and the pipetting sequence will begin.
16. If running more than one assay, ensure that the carousel access door is closed, and press **RUN**. If the instrument is not programmed to prompt for the sample loadlist (**System 6.14** = 0), go to Step 18. If it is programmed to record this information, the sample loadlist prints and the display reads:

ASSAY LIST OK?

Press **STORE/YES** if the list is correct, and proceed to the next step.

Press **NEXT/NO** if the list is incorrect. The display updates with:

LOC 1 ASSAY # \_ \_

Press **NEXT** to scroll forward or **EDIT** to scroll backward through the sample carousel locations and patient ID numbers until the incorrect entry is reached.

17. Once the list has been corrected, repeat Step 16.

**NOTES:** After entering a valid reagent loadlist and a sample loadlist, the instrument stores the lists temporarily. If the run is aborted, the display reads [SAME RGT CRSL?] and [SAME SAMPLE LST?] when restarting the run.

If the configurations of the reagent carousel and the sample carousel remain the same, press **STORE** for both messages to accept the lists.

If the configuration is different, press **NEXT** for both messages and repeat the applicable steps detailed above.

This feature is active only in the random access mode of operation. The feature only appears after a run is aborted and only if that run is followed by a random access run.

18. Wait for an entire printout. The run is complete when the display reads:

DONE - REMOVE RPAK

---

**Batch**

The following pages detail the operating procedures for the batch mode of testing. These procedures are presented in the following order:

- Initialization Checks
- Assay Process Sequence
- Calibration Procedure
- Assay Procedure
- Barcode Override

## Initialization Checks

Prior to testing in the batch mode, the TDxFLx<sup>®</sup> System performs fifteen initialization checks. After the **RUN** key is pressed, the following sequence occurs:

1. The reagent carousel seeks its home position. If the home flag is not sensed, the system assumes that a batch run is to be performed.
2. The system checks for a valid date.
3. The waste cup counter is updated for the number of primes since the last “**CHECK WASTE CUP**” message was displayed and printed.
4. The buffer sensor verifies that sufficient buffer is present.
5. The software checks for the presence of the waste container.
6. The system checks the horizontal and vertical movement of the boom arm as it seeks the R-boom and Z-boom home positions.
7. The TDxFLx<sup>®</sup> System checks for the sample carousel and verifies that the carousel is locked.
8. The boom-arm barcode reader reads the carousel label and the reagent pack label and the assay name is displayed.
9. The door sensor checks to see that the door is closed.
10. The system turns on the lamp and checks the intensity.
11. Position 21 is rotated in front of the optics to check for the presence of a Turbo<sup>®</sup> Carousel.
12. The cuvette sensor counts by reflectance and looks for missing or extra cuvettes.
13. The system verifies syringe and valve movement and home positions.
14. The liquid-level sensor checks reagent levels to ensure that there is sufficient reagent in the reagent pack.
15. The ambient temperature is checked, and the thermal detector verifies that the cuvette surface temperature is 35°C.

### Assay Process Sequence

The process sequence for a batch assay occurs automatically after the analyzer door is closed, the **RUN** key is pressed and the system passes all initialization checks. The batch assay sequence begins:

Step 1 The carousel moves sample/cuvette Position 1 to the dispense axis.

Step 2 The first dispense cycle begins. The reagent is dispensed and the sample is diluted in preparation for background readings. The display reads:

REV 1 PIPETTING

Step 3 The carousel rotates for Rev 1 pipetting until the first cuvette reaches the optical path. Background intensity readings, when required, are taken and stored for each cuvette. The display reads:

BLANK READING

Step 4 The carousel rotates for blank readings until the first position returns to the dispense axis. The second cycle begins, and the display reads:

REV 2 PIPETTING

Step 5 When the last sample position is diluted and dispensed, the carousel revolves to maintain cuvette temperature for a time specific for the assay type. The display reads:

INCUBATING

Step 6 Final intensity readings are taken on each cuvette. The display reads:

FINAL READING

Step 7 Final intensity readings are corrected for background intensities. Polarization or percent intensity values, depending on assay technology, are calculated and converted to the appropriate concentration units.

Step 8 The assay results are printed.

Step 9 The paper supply is checked.

Step 10 The display reads:

DONE - REMOVE RPAK

beeps, then displays

READY

If the carousel is not removed within 5 minutes following the completion of the run, the instrument beeps and displays:

REMOVE CAROUSEL

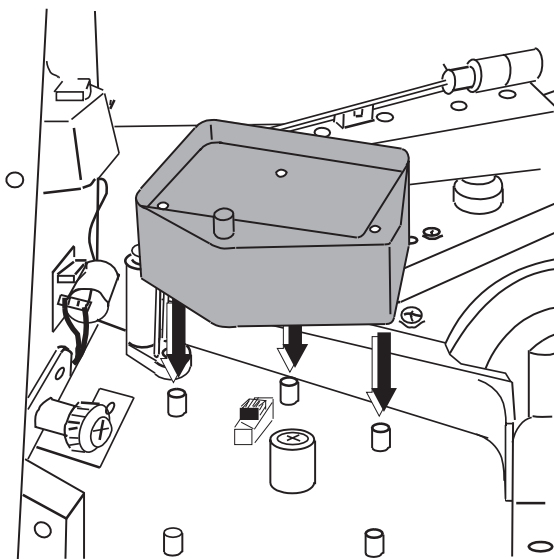


## Calibration Procedure

The following paragraphs present the step-by-step procedure for performing a batch calibration run.

### System Set-Up

- Ensure that all maintenance has been performed if this is the first run of the shift. Refer to **Section 5.0** for maintenance procedures.
- Install the **batch-pack adapter**. Position the batch-pack adapter over the three rear reagent-carousel support pins. Ensure that the adapter is seated securely on the reagent platform.



- The TDxFLx<sup>®</sup> System stores a calibration curve for each batch assay. The batch calibration curves are separate and distinct from the calibration curves stored for the random access and unit dose versions of the same assay. Therefore, prior to running an assay, the instrument must be calibrated for that assay in the mode being run.
- Ensure that assay parameter .6 CAL REPS is 2. Press **ASSAY XX.6 DISPLAY**. If 2, press **STOP**, if not, press **EDIT 2 STORE STOP**.
- If running an abused drug assay calibration, ensure the numerical print option (T Print, **System 6.7** =0) has been selected. Press **SYSTEM 6.7 DISPLAY**. If 0, press **STOP**, if not press **EDIT 0 STORE STOP**. This allows the system to print numerical values for control samples; thus allowing verification of calibration acceptability as outlined in the **Calibration Acceptability Criteria** section.
- If pretreatment of calibrators and controls is required, follow the pretreatment procedure as described in the appropriate assay insert in the assays manual.
- Program parameter options as desired. Refer to **Programmable Options** in the Introduction section for details.

### Preparing the Calibration Carousel

1. Select a calibration carousel.
2. Load 15\* sample cartridges and cuvettes. Begin with Position 1 and continue sequentially. Do not skip a position. Ensure that all cuvettes are upright and disposables are clean and free of foreign matter.

\*For some assays, only 14 sample cartridges and cuvettes are required, as there are only two controls (H and L).

3. Lock cuvettes into position by turning the locking mechanism clockwise until it clicks.
4. Invert the calibrator pack gently five times. Pipette, in duplicate, a minimum of 50 µL for most assays, (refer to the assays manual for specific sample volume), of calibrator A - F into sample wells 1 through 12. Avoid splashing, foaming, or bubbling.

Example: Pipette A into Positions 1 and 2, B into 3 and 4, C into 5 and 6, etc.

Recap each vial as it is used, and return the pack to the proper storage described on the labeling.

5. Invert the control pack gently five times. Pipette a minimum of 50 µL for most assays, (refer to the assays manual for specific sample volume), of H, M, and L controls into sample wells 13 through 15. Avoid splashing, foaming, or bubbling. Positions 16 through 20 are available for patient samples.

**NOTE:** If the Display Data option (System 4.2) is being used, do not run any samples (unknowns or controls) after the last calibrator because they will not appear in the display.

For some assays, do not run controls on the calibration run. No results will be printed for the controls. Refer to the specific assays procedure in the assays manual.

Recap each control vial as it is used and return the pack to proper storage as described on the labeling.

6. Inspect the sample wells for bubbles and remove any bubbles with applicator sticks. Use a different applicator stick for each level of calibrator or control.

### Preparing the Reagent Pack

7. Select the appropriate reagent pack.
8. Invert gently five times. Open the batch reagent pack and check to be sure the vials read S, T, P.  
**NOTE:** Some vials read P, T, P. 4-pot reagent pack vials read W, S, T, P.
9. Remove the vial caps and place them upside-down in the lid spaces provided.
10. Inspect the surface of the liquid in the vials for bubbles and remove any bubbles with applicator sticks. Use a different applicator stick for each vial.

### Run Calibration

11. Ensure that the **batch-pack adapter** is installed properly.
12. Insert the **reagent pack** into the proper position on the **batch-pack adapter**.
13. Place the loaded calibration carousel into the instrument. Close all access doors.
14. Press **RUN**.
15. If the instrument is not programmed to record the operator ID (**System 6.3** = 0), go to Step 16. If it is programmed to record this number, the display reads:

OP ID?

Enter the ID number using the barcode scanner or the numerical keypad for this input. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

16. Steps 17 and **18** are activated under specific circumstances. Most of the time, they are skipped by the instrument; therefore, the operator may skip these and go directly to **Step 20**. If these steps apply to the run, then the instrument prompts for this input. The operator should then proceed with the following steps.
17. If the boom-arm barcode reader fails to detect the sample carousel label properly, the instrument will not know what type of run to perform.

The display reads:

CALIBRATION?

Press **STORE** and continue with **Step 19**.

18. If the instrument detects a new/unused batch reagent pack, the display reads:

RGT # ? \_ \_ \_ \_ \_

Enter the reagent lot number and press **STORE**. If the number is incorrect, press **CLEAR** and enter the correct number.

**NOTE:** This step is active only when a new/unused batch reagent pack is detected. The instrument skips this step after the reagent pack is initialized.

19. Verify that the correct assay name and the word [CALIBRATION] have displayed before leaving the instrument. The assay name and tests used [t used = XXX] or tests left [t left = XXX] should be displayed on the reagent display. If the assay name displayed is incorrect, press **STOP** and refer to the **barcode-override procedure** in this section.
20. The observed data and the calculated curve print at the end of the run. Do **NOT** press **STOP** before the printout is complete. Doing so terminates processing and prevents storage of the calibration curve. When calibration is complete, the instrument displays:

DONE - REMOVE RPAK

### Clean-Up

21. If the reagent pack is not to be used **immediately**, it should be removed, recapped, and returned to proper storage as described on the labeling.
22. Remove the calibration carousel, close the access door, and examine the sample cartridges for evidence of splashing or foaming.

**CAUTION:** If splashing or foaming is observed, do not report results. These symptoms indicate a problem and require corrective action. Refer to **Section 6.0** under **Observed Problems**.

23. If no splashing or foaming is observed, discard the contents of the calibration carousel. All waste should be disposed of as suitable for patient samples. Refer to **decontamination** and **spill clean-up** in Section 1.0 under Operational Precautions and Limitations.
24. If separation of plastic and glass is not required, unlock the carousel, invert over a receptacle and discard the cartridges and cuvettes all at once. Ensure all sample cartridges and cuvettes have been removed.

25. If separation of glass and plastic is required, place your fingers inside the bottom of the carousel under the locking mechanism knob. Invert the carousel over a receptacle and discard the sample cartridges. Unlock the carousel, invert over a receptacle and discard the cuvettes. Ensure all sample cartridges and cuvettes have been removed.
26. Verify the calibration acceptability.

#### **Calibration Acceptability Criteria (Operator)**

The operator verifies acceptability of a calibration curve by three criteria:

1. The PERR (polarization error) or ERR (percent error) values must be within the acceptable range indicated in the assay manual insert.
2. The RMSE (root mean squared error) must be within the acceptable range indicated in the assay manual insert.
3. Each level of control must be within the acceptable ranges indicated in the assay manual insert.

If any of these values are out of range, determine the cause and recalibrate, if necessary. Refer to **Section 6.0 Observed Problems** under Calibration Fails to Meet Specification.

Reading Batch Calibration Printouts

Therapeutic Drug or Hormone Calibration Printouts

The following printout is typical of a therapeutic drug or hormone calibration.

<b>A</b>	DATE:			
<b>B</b>	TIME:			
<b>C</b>	SERIAL #:			
<b>D</b>	LOCK=	1		
<b>E</b>	OP ID #:			
<b>F</b>	RGT LOT #:			
<b>G</b>	EXP DATE:			
<b>H</b>	ASSAY:	THEOPHYLLINE		
	CALIBRATION			
<b>I</b>	VOL=	2.00		
<b>J</b>	REPS=	2		
<b>K</b>	GAIN=	40		
<b>L</b>	CONC=	UG/ML		
		<b>NET N</b>	<b>NET O</b>	<b>P</b>
<b>M</b>	I.D.	P	I	I
	1 A	242.39	7105.84	460.6
	2 A	244.11	7488.64	452.9
	3 B	217.79	7276.94	472.1
	4 B	217.11	7276.94	472.1
	5 C	196.02	7551.34	419.3
	6 C	196.99	7323.04	422.9
	7 D	169.24	7572.54	433.4
	8 D	167.98	7654.14	431.1
	9 E	135.77	7871.24	440.7
	10 E	135.06	7776.14	448.0
	11 F	101.86	8023.64	444.8
	12 F	102.31	8096.44	452.1
		<b>Q</b>	<b>R</b>	<b>S</b>
	I.D.	CONC	AVGP	FITP
	A	0.00	243.25	243.25
	B	2.50	217.45	216.80
	C	5.00	196.51	197.09
	D	10.00	168.61	168.80
	E	20.00	135.42	134.95
	F	40.00	102.09	102.27
				<b>T</b>
				PERR
	A			0.00
	B			0.65
	C			-0.58
	D			-0.19
	E			0.47
	F			0.18
<b>U</b>	RMSE=	0.36		
		SAMPLES		
	LOC	CONC	NET P	BLK I
<b>V</b>	13	7.32LOW	182.49	433.40
	14	12.22	159.30	427.96
	15	25.20HI	123.57	427.91
<b>W</b>	TESTS USED =	XXX		

- A. Date of calibration
- B. Time of calibration
- C. Serial number of instrument
- D. Door lock status (0 = off, 1 = on)
- E. Operator ID number (optional feature)
- F. Reagent lot number (optional feature)
- G. Expiration date (optional feature)
- H. Name of assay being calibrated
- I. Volume - final amount of calibrator in cuvette
- J. Number of calibrator replicates
- K. Gain
- L. Concentration units
- M. Position of calibrators in carousel
- N. Net polarization - net intensity readings calculated as a polarization value
- O. Net intensity - fluorescence intensity readings after tracer has been added and correction for background readings made
- P. Blank intensity - calibrator background intensity
- Q. Expected concentrations of calibrators
- R. Average polarization - the average of the net polarizations calculated for each replicated calibrator
- S. Fit polarization - the polarization values obtained when the calibration curve is fitted as close as possible to the average polarizations calculated
- T. Polarization error - calculated as the average polarization (AVGP) for each calibrator minus the fit polarization (FITP) for each calibrator
- U. Root Mean Square Error - a measurement of standard deviation of the PERRs
- V. Concentrations, net polarizations, and blank intensity readings of the control samples
- W. Number of tests used or tests left on the reagent pack up to date

Clinical Chemistry Calibration Printouts

A printout for a clinical chemistry calibration is similar to a therapeutic drug or hormone batch calibration printout. Some column headings differ, as shown in the printout below.

DATE:				
TIME:				
SERIAL #:				
LOCK= 1				
EXP DATE:				
ASSAY: GLUCOSE				
CALIBRATION				
VOL= 3.00				
REPS= 2				
GAIN= 5				
CONC= MG/DL				
I.D.                      PERCENT                      FINAL V                      INITIAL V				
1	A	93.33	10388.31	11130.4
2	A	95.10	10598.61	11144.7
3	B	67.15	7381.81	10993.5
4	B	66.14	7353.41	11118.6
5	C	46.96	5176.81	11023.6
6	C	46.28	5154.71	11138.9
7	D	33.63	3707.31	11022.2
8	D	33.65	3716.11	11043.2
9	E	23.58	2642.81	11208.1
10	E	24.14	2635.41	10915.9
11	F	17.62	1964.51	11146.2
12	F	17.03	1893.11	11113.5
I.D.                      CONC                      AVG                      FIT                      ERR				
A	0.00	94.22	94.22	0.00
B	100.00	66.64	66.61	0.03
C	200.00	46.62	46.74	-0.12
D	300.00	33.64	33.40	0.24
E	400.00	23.86	24.07	-0.21
F	500.00	17.33	17.26	0.07
RMSE= 0.12				
LOC                      SAMPLES                      CONC                      PERCENT                      FINAL V				
G	13	253.36HI	39.00	4385.69
	14	110.23HI	64.18	7179.25
	15	72.65	73.60	8064.64
H TESTS USED = XXX				

- A. Percentage of blue and green light not absorbed by the chromogen in calibrators
- B. Final vertical intensity readings of the calibrators
- C. Initial vertical intensity readings of the calibrators
- D. Average of percent readings – the average of the percent readings for each replicated calibrator
- E. Fit percent readings
- F. Error – calculated as the average percent reading minus the fit percent reading
- G. Patient concentrations, percent of light not absorbed by the chromogen, and final vertical intensity readings of the control samples
- H. Number of tests used or tests left on the reagent pack up to date

Abused Drug Calibration Printouts

This printout is similar to a therapeutic drug or hormone batch calibration printout (exceptions noted). This example was obtained with **System 6.7** (T Print) set to 0.

DATE:				
TIME:				
SERIAL #:				
LOCK= 1				
EXP DATE:				
ASSAY: AMPHET/METH U <b>A</b>				
CALIBRATION				
VOL= 8.00				
REPS= 2				
GAIN= 20				
CONC = NG/ML				
I.D.	NET	NET	BLANK	
	P	I	I	
1 A	211.25	4776.2	596.4	
2 A	210.96	4972.2	611.6	
3 B	194.98	4972.6	490.0	
4 B	193.26	4961.7	496.5	
5 C	183.96	5045.7	461.8	
6 C	183.85	4990.7	468.8	
7 D	165.65	5038.6	468.5	
8 D	166.12	5055.3	462.5	
9 E	150.14	5179.4	629.2	
10 E	149.10	5070.8	620.3	
11 F	135.84	5243.6	615.7	
12 F	134.99	5292.6	624.9	
I.D.	CONC	AVGP	FITP	PERR
A	0.00	211.11	211.11	0.00
B	150.00	194.12	194.14	-0.02
C	300.00	183.91	184.00	-0.09
D	1000.00	165.89	165.61	0.28
E	3000.00	149.62	149.89	-0.27
F	8000.00	135.42	135.33	0.09
RMSE= 0.14				
STORED THRESHOLD = 300.00 <b>B</b>				
SAMPLES				
LOC	CONC	NET P	BLK I	
<b>C</b> {	13	610.00 >= T	170.12	511.06
	14	1880.00 >= T	144.86	510.59
TESTS USED = XXX <b>D</b>				

- A. U - indicates a urine assay.
- B. Same value as assay parameter .4 (THRSHLD).
- C. >= T - indicates concentration is greater than or equal to the threshold.
- D. Number of tests used or tests left on the reagent pack up to date

The following paragraphs explain the print options available for an abused drug calibration printout using different **System 6.7** settings.

- If **SYSTEM 6.7** = 0, the printout is similar to a therapeutic drug or hormone batch calibration printout, except that >= T (greater than or equal to threshold) prints following numerical results above the stored threshold.
- If **SYSTEM 6.7** = 1, then >= THRESHOLD or NONE DETECTED prints in place of a numerical result.
- If **SYSTEM 6.7** = 1, a numerical result may be obtained by editing **System 6.7** to 0 and reprinting the calibration curve data by pressing **SYSTEM 4.1 RUN**. Reprint must be performed before any further operations are initiated on the TDxFLx<sup>®</sup> Analyzer; otherwise, the calibration and control data will not be available for retrieval.

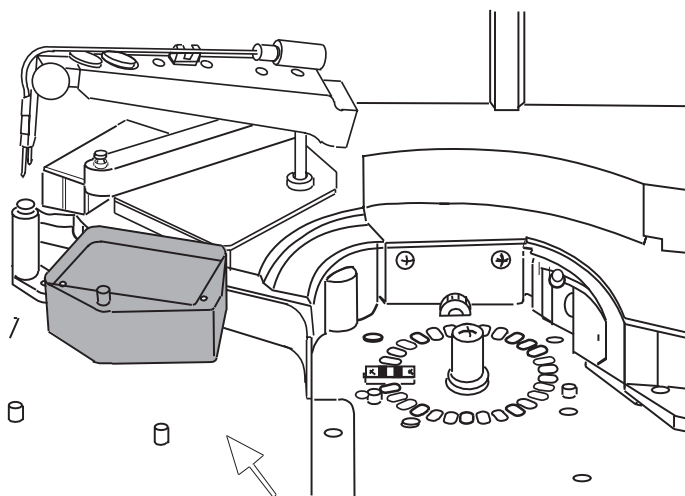


## Assay Procedure

The following paragraphs present the step-by-step procedure for performing a batch assay run.

### System Set-Up

- Ensure that maintenance has been performed if this is the first run of the shift. Refer to **Section 5.0** for maintenance procedures.
- Ensure **batch-pack adapter** is properly installed.



- Ensure that a calibration curve has been stored for the assay being performed. To check the calibration date for a specific assay, press **ASSAY XX.22 DISPLAY**. The calibration date is displayed.
- If running an abused drug assay, ensure the numerical print option desired (T Print, **System 6.7**) has been selected. Press **SYSTEM 6.7 DISPLAY**. If correct, press **STOP**. If incorrect, press **EDIT 0** or **1** (as desired) **STORE STOP**.
- If pretreatment of samples and controls is required, follow the procedure described in the appropriate assay section in the assays manual.
- Program parameter options as desired. Refer to **Programmable Options** in the Introduction section for details.

### **Preparing the Sample Carousel**

1. Select a numbered sample carousel.
2. Load the carousel with one sample cartridge and cuvette for each sample to be assayed. Ensure that all cuvettes are upright and disposables are clean and free of foreign matter. Some assays require a modified carousel set-up procedure. Refer to the specific assays procedure in the assays manual. Begin with Position 1 and continue sequentially. Do not skip positions.
3. Lock cuvettes into the carousel by turning the locking mechanism clockwise until it clicks.
4. Pipette a minimum of 50  $\mu\text{L}$  (for most assays) of patient sample into sample wells for each position being used. Refer to the assays manual for the specific sample volume. Avoid splashing, foaming, or bubbling.
5. Inspect the sample wells for bubbles and remove any bubbles with applicator sticks. Use a different applicator stick for each sample cartridge.

### **Preparing the Reagent Pack**

6. Select the appropriate reagent pack.
7. Invert gently five times. Open the reagent pack and check to be sure the vials read S, T, P.

**NOTE:** Some vials read P, T, P. 4-pot reagent pack vials read W, S, T, P.

8. Remove the vial caps and place them upside-down in the lid spaces provided.
9. Inspect the vials for bubbles and remove any bubbles with applicator sticks. Use a different applicator stick for each vial.

### Run Assay

10. Insert the **reagent pack** into the **batch-pack adapter**.
11. Place the loaded assay carousel into the instrument.
12. Close the access door.
13. Press **RUN**.
14. If the instrument is not programmed to record the operator ID (**System 6.3** = 0), go to Step 15. If it is programmed to record this number, the display reads:

OP ID?

Enter the ID number using the barcode scanner or the numerical keypad for this input. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

15. Steps 16 and **17** are activated under specific circumstances. Usually these steps are skipped by the instrument; therefore, the operator may skip these and go directly to **Step 18**. If these steps apply, then the instrument prompts for this input. The operator should then follow these steps.
16. If the boom-arm barcode reader failed to detect the sample carousel barcode label properly, the instrument will not know what type of run to perform.

The display reads:

CALIBRATION?

Press **NEXT**. The display updates with

CAROUSEL # ?

Enter the number of the carousel, press **STORE**, and continue with **Step 18**.

17. If the instrument detects a new/unused batch reagent pack, the display reads:

RGT # ? \_ \_ \_ \_ \_

Enter the corresponding lot number of the batch reagent pack and press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number. Repeat this step for all occurrences.

The lot number prompt is only activated the first time a new/unused batch reagent pack is detected. The instrument skips this step after a reagent pack is initialized into the system.

18. If the instrument is not programmed to record the patient ID number (**System 6.6** = 0), go to Step 19. If the instrument is programmed to record the patient ID number, the display reads:

ID 1 ?

Enter the patient ID number by using either the barcode scanner or the numerical keypad. Controls may be identified by scanning the TDxFLx<sup>®</sup> QC Barcode label. If the numerical keypad is used, press **STORE** after the correct number is entered. If an entry error is made, press **CLEAR** and enter the correct number.

19. Before leaving the instrument, verify that the correct assay name and tests used [t used = XXX] or tests left [t left = XXX] is displayed on the reagent display. If the assay name displayed is incorrect, press **STOP** and refer to the **barcode-override procedure** in this section.
20. Wait for an entire printout. The assay is complete when the display reads:

DONE - REMOVE RPAK

### Clean-Up

21. If the reagent pack is not to be used **immediately**, it should be removed, recapped and placed at proper storage, as described on the labeling.
22. Remove the carousel, close the access door, and examine the sample cartridges for evidence of splashing or foaming.

**CAUTION: If splashing or foaming is observed, do not report results. These symptoms indicate a problem and require corrective action. Refer to **Section 6.0** under Observed Problems.**

23. If no splashing or foaming is observed, discard the contents of the carousel. All waste should be disposed of as suitable for patient samples. Refer to **decontamination** and **spill clean-up** in Section 1.0 under Operational Precautions and Limitations.
24. If separation of glass and plastic is not required, unlock the carousel, invert over a receptacle, and discard the cartridges and cuvettes all at once. Ensure all sample cartridges and cuvettes have been removed.
25. If separation of glass and plastic is required, place your fingers inside the bottom of the carousel under the locking mechanism knob. Invert the carousel over a receptacle and discard the sample cartridges. Unlock the carousel, invert over a receptacle, and discard the cuvettes. Ensure all sample cartridges and cuvettes have been removed.

Reading Batch Assay  
Printouts

Therapeutic Drug or Hormone Assay Printouts

The following printout is typical of a therapeutic drug or hormone batch assay. The patient results that are to be reported are found in the column entitled CONC.

A

DATE:

B

TIME:

C

SERIAL #:

D

LOCK= 1

E

OP ID #:

F

RGT LOT #:

G

EXP DATE:

H

ASSAY: THEOPHYLLINE

I

CAROUSEL: 1

J

SPLVOL= 2.0

K

REPS= 1

L

GAIN= 40

M

CALIB. DATE:

N

CALIB. TIME:

O

CONC= UG/ML

S

SAMPLES  
CONC

R

NET P

Q

BLK I

P

LOC

16.63 LOW

179.82

423.57

2

11.73

155.83

1971.69 HI

3

25.20 HI

119.64

427.91

4

LOW

220.19

379.79

5

HI

82.74

405.72

T

TESTS USED = XXX

- A.

Date of assay run
- B.

Time of assay run
- C.

Serial number of instrument
- D.

Door lock status (0 = off, 1 = on)
- E.

Operator ID number (optional feature)
- F.

Reagent lot number (optional feature)
- G.

Expiration date (optional feature)
- H.

Name of assay
- I.

Assay carousel number
- J.

Sample volume - final amount of sample in the cuvette in microliters
- K.

Number of sample replicates
- L.

Gain
- M.

Date of last calibration stored
- N.

Time of last calibration stored
- O.

Concentration units
- P.

Location - position in carousel
- Q.

Blank intensity - serum background intensity reading
- R.

Net polarization - polarization of sample corrected for background reading
- S.

Concentration - net polarization converted to concentration units
- T.

Number of tests used or tests left on reagent pack to date

### HI and LOW Readings

The following paragraphs describe the HI and LOW flags that can appear on the printout. More detailed information is provided in [Section 6.0 Troubleshooting](#).

#### HI Printed After BLK I Reading

- If the blank intensity or background reading exceeds the maximum expected reading (assay parameter .20), HI prints after the blank value.
- If a HI flag appears here, the patient sample may contain another drug or substance that is adding fluorescence.
- If the BLK I value is less than three times the MN TR value, the results are reportable. The MN TR value for a specific assay can be displayed by first pressing **ASSAY PRINT** to obtain a list of available assays. Locate the number corresponding to the name of the assay and press **ASSAY (XX) .21 DISPLAY**.
- If the BLK I value is more than three times the MN TR, manually dilute the sample and repeat the run or rerun the sample using [dilution protocol](#).
- If all BLK I readings show HI, it is not an isolated case. Common causes are:
  - an open access door
  - contaminated buffer
  - lamp cover off or seated incorrectly
  - contaminated or previously used cuvettes
  - contaminated P reagent vial

#### HI or LOW Printed After CONC Result

- If any result is outside of the programmed therapeutic range (assay parameters .3 and .4), the patient result is flagged as HI or LOW. This alerts the operator to an out-of-range sample. The results should be given special attention and the responsible personnel notified per laboratory procedure.

### HI or LOW Printed Instead of CONC Result

- If the Net P value is outside the span of the calibration curve, HI or LOW prints instead of the numeric result.
- If LOW prints, see [Section 6.0 Troubleshooting](#) before proceeding further.
- If LOW is repeated after following all troubleshooting, the concentration may be reported as less than the sensitivity of the specific assay. The sensitivity ranges are provided in the assays manual.
- If HI prints, the test should be rerun using Dilution Protocol. Refer to the [Dilution Protocol procedure](#) in this section. If Dilution Protocol is not allowed for the assay, rerun the test following a manual dilution of the sample. Refer to the assays manual for specific instructions for each assay.



Clinical Chemistry Assay Printouts

A printout for a clinical chemistry assay is similar to a therapeutic drug or hormone batch assay printout. Some column headings differ, as shown in the printout below. The patient results that are to be reported are found in the column labeled SAMPLES.

DATE:  
TIME:  
SERIAL #:  
LOCK= 1  
OP ID #:  
RGT LOT #:  
EXP DATE:  
ASSAY: GLUCOSE  
  
CAROUSEL: 2  
  
SPLVOL= 3.00  
REPS= 1  
GAIN= 5  
CALIB. DATE:  
CALIB. TIME:  
  
CONC= MG/DL

	<b>A</b>		<b>B</b>	<b>C</b>
	SAMPLES		PERCENT	FINAL V
LOC	CONC			
1	60.25	LOW	70.90	7949.95
2	100.01		63.58	21224.30HI
3	244.06	HI	38.67	4464.72
4	HI		13.42	1455.23
5	LOW		90.54	11130.43

TESTS USED = XXX **D**

- A. Final concentration in patient sample
- B. Percentage of blue and green light not absorbed by the chromogen
- C. Final vertical intensity reading
- D. Number of tests used or tests left on reagent pack to date

### HI and LOW Readings

The following paragraphs explain the HI and LOW flags that may appear on the clinical chemistry printout.

#### HI or LOW Printed After CONC Result

- If any result is outside the programmed normal range (assay parameters .3 and .4), the patient result is flagged as HI or LOW. This alerts the operator to an out-of-range sample. The results should be given special attention and the responsible personnel notified per laboratory procedure.

#### HI or LOW Printed Instead of CONC Result

- If the percent value is outside the span of the calibration curve, a HI or LOW prints instead of a numeric result.
- If LOW prints, see [Section 6.0 Troubleshooting](#) for corrective action.
- If HI prints, the test should be rerun using Dilution Protocol. Refer to the [Dilution Protocol procedure](#) in this section. If Dilution Protocol is not allowed for the assay, rerun the test following a manual dilution of the sample. Refer to the assays manual for Dilution Protocol availability for each assay.

#### HI Printed After Final V Result

- If the blank intensity reading is greater than the MX BKG (assay parameter .20), HI prints after the Final V value.

Abused Drug Assay Printouts

A printout for an abused drug assay is similar to a therapeutic drug or hormone batch assay printout. The patient results that are to be reported are found in the column labeled CONC. This example was obtained with **System 6.7** (T Print) set to **0** and the patient ID option is set to **1**, (1 = on).

DATE:  
TIME:  
SERIAL #:  
LOCK= 1  
OP ID:  
RGT LOT #:  
EXP DATE: **A**  
ASSAY: AMPHET/METH U  
CAROUSEL: 3  
SPLVOL= 8.00  
REPS= 1  
GAIN= 20  
CALIB. DATE:  
CALIB. TIME:  
CONC= NG/ML

STORED THRESHOLD = 300.00 **B**

LOC		SAMPLES		
	<b>C</b>	CONC	NET P	BLK I
1		ID # 12		
		LOW	214.71	716.34
2		ID # 15		
		> MX BKG		1498.43 HI
3		ID # 34		
		LOW	213.85	717.72
4	<b>D</b>	ID # 45		
		530.00> = T	170.19	624.07
5		ID # 90		
		530.00 > = T	170.36	625.90
6		ID # 95		
		> MX BKG		1506.15 HI

TESTS USED = XXX **E**

- A. Expiration date of the reagent pack
- B. Threshold value - same value as assay parameter .4 THRSHLD
- C. Patient ID - patient identification
- D. > = T - concentration is greater than or equal to the Threshold
- E. Number of tests used or tests left on reagent pack to date

SYSTEM 6.7 = 0

- If **SYSTEM 6.7** = 0, then > = T (greater than or equal to threshold) prints following the numerical concentration result if that concentration is higher than the stored threshold. If BLK I exceeds assay parameter .20 MX BKG, > MX BKG prints under CONC.
- If a HI flag appears, the patient sample must not be diluted and rerun. Assay parameter .20 (MX BKG) should not be edited to a greater value than is found for that assay in the assays manual.
- If LOW prints instead of a CONC result, the mP reading for the sample is higher than the mP used in the calibration curve for the A Calibrator. More detailed information is provided in **Section 6.0 Troubleshooting**.

Below is an example of the printout when **System 6.7** (T Print) is set to **1**, and **System 6.6** (PAT ID) is set to **0**, (0 = off).

```
DATE:
TIME:
SERIAL #:
LOCK= 1
OP ID:
RGT LOT #:
EXP DATE:
ASSAY: AMPHET/METH U

CAROUSEL: 3

SPLVOL= 8.00
REPS= 1
GAIN= 20
CALIB. DATE:
CALIB. TIME:

CONC= NG/ML

        STORED THRESHOLD = 300.00
        SAMPLES
LOC  CONC          BLK I
1    NONE DETECTED
2    > MX BKG
3    NONE DETECTED
4    > = THRESHOLD
5    > = THRESHOLD
6    > MX BKG

TESTS USED = XXX
```

**SYSTEM 6.7 = 1**

- If **SYSTEM 6.7** = 1, then > = THRESHOLD or NONE DETECTED prints under CONC and after the location number. No numerical concentration result is printed. No NET P is printed.
- BLK I is not printed except when the background intensity exceeds assay parameter .20 MX BKG. In this case > MX BKG prints under CONC and HI prints following the BLK I reading.
- If a HI flag appears, the patient sample must not be diluted and rerun. Assay parameter .20 (MX BKG) should not be edited to a greater value than is found for that assay in the assay parameters section of the assays manual insert.
- If NONE DETECTED prints instead of a CONC result, the sample value is less than the stored threshold. See the Troubleshooting section under **Printed Error Codes** for more information.
- With either setting of **6.7**, STORED THRESHOLD = prints before the assay results. The stored threshold value, printed, is the same value as assay parameter .4 (THRSHLD).

## Barcode Override

Barcode-override procedures may be used if the barcode label is misread. This procedure is provided only to help you continue the run but should not be used routinely. If a barcode problem arises, finish the run and then refer to [Section 6.0 Troubleshooting](#) for assistance.

If an incorrect assay name is displayed after **RUN** is pressed:

1. Press **STOP**. The display returns to

READY

2. Carefully remove the batch reagent pack and verify that the correct reagent pack was loaded.
3. Refer to the assay list printout. If not available, press **ASSAY PRINT**. Select from this list the appropriate assay.
4. Press **ASSAY**, enter the assay number, and press **RUN**. The display reads:

#= \_ \_ \_ \_ \_

5. Enter the 13-digit reagent barcode number using the barcode scanner or the numerical keypad.

### Barcode Scanner

Press the button and aim the scanner at the barcode label. Ensure the scanner light encompasses the entire barcode label of the reagent pack. The scanner beeps when it recognizes the label. If the scanner does not read a label within 60 seconds, it automatically shuts off.

### Numerical Keypad

Enter the 13-digit barcode label number of the reagent pack. Press **STORE** once the correct number has been entered. If an incorrect entry was made, press **CLEAR** and enter the correct number.

6. If the instrument detects a new/unused batch reagent pack, the display reads:

RGT # ? \_ \_ \_ \_ \_

Enter the reagent lot number and press **STORE**. If the number is incorrect, press **CLEAR** and enter the correct number.

**NOTE:** This step is active only when a new/unused batch reagent pack is detected. The instrument skips this step after the reagent pack is initialized into the system.

7. The display updates with

CALIBRATION?

If performing a calibration run, press **STORE**. This entry activates the calibration procedure.

8. If performing an assay run, press **NEXT**. The display reads:

CAROUSEL # ?

Enter the carousel number and press **STORE**. This entry activates the assay run.

9. Verify that the correct assay name and the number of tests used or tests left are displayed on the reagent display. Results print upon completion.

**NOTE:** This procedure is modified for assays utilizing interactive dilution protocol. Refer to the Interactive Dilution Protocol section of the appropriate assay manual insert.

**Unit Dose**

The following pages detail the operating procedures for the unit dose mode of testing. These procedures are presented in the following order:

- Initialization Checks
- Assay Process Sequence
- Calibration Procedure
- Assay Procedure
- Barcode Override

## Initialization Checks

Prior to testing in the unit dose mode of operation, the TDxFLx<sup>®</sup> System performs fifteen initialization checks. After the **RUN** key is pressed, the following sequence occurs:

1. The reagent carousel seeks its home position. If the home flag is not sensed, the system assumes that a unit dose run is to be performed.
2. The system checks for a valid date.
3. The waste cup counter is updated for the number of primes since the last “**CHECK WASTE CUP**” message was displayed and printed.
4. The buffer sensor verifies that sufficient buffer is present.
5. The software checks for the presence of the waste container.
6. The system checks the horizontal and vertical movement of the boom arm as it seeks the R-Boom and Z-Boom home positions.
7. The TDxFLx<sup>®</sup> System checks for the sample carousel and verifies that the carousel is locked.
8. The boom-arm barcode reader reads the carousel label.
9. The cuvette sensor counts cuvettes by reflectance and looks for missing or extra cuvettes. The barcode reader reads the unit dose cartridges and displays all assay names. All assay locations and calibration dates are printed. In addition any problems associated with running the assay such as “ILLEGAL SPL VOL” are printed.
10. The door sensor checks to see that the door is closed.
11. The system turns on the lamp and checks the intensity.
12. Position 21 is rotated in front of the optics to check for the presence of a Turbo<sup>®</sup> Carousel.
13. The ambient temperature is checked.
14. The system verifies syringe and valve movement and home positions.
15. The thermal detector verifies that the cuvette surface temperature is 35°C.



Assay Process  
Sequence

The process sequence for a unit dose assay occurs automatically after the analyzer door is closed, the **RUN** key is pressed, and the system has passed initialization checks. The sequence follows:

- Step 1    The unit dose carousel moves sample number 1 to the dispense axis.
- Step 2    The first dispense cycle begins. Appropriate reagent is dispensed and the sample is diluted for background reading if required. The display reads:

REV 1 PIPETTING

- Step 3    As the unit dose carousel rotates during Rev 1 pipetting, and the first cuvette reaches the optical path, a background intensity reading, when required, is taken and stored in memory. The display reads:

BLANK READING

- Step 4    After Rev 1 pipetting and as blank readings continue, the first sample position is returned to the dispense axis and the second dispense cycle begins. The display reads:

REV 2 PIPETTING

- Step 5    When sample number 1 reaches the optical path, and at the completion of Rev 2 pipetting for sample number 11, a final intensity reading is taken and the display reads:

FINAL READING

- The display alternates between REV 2 PIPETTING and FINAL READING until Rev 2 Pipetting is completed for all samples.
- Step 6    When Rev 2 pipetting is completed, the unit dose carousel rotates and the display reads:

INCUBATING

At the same time, a final intensity reading is taken on the remaining samples. The display reads:

**FINAL READING**

The display alternates between INCUBATING and FINAL READING until the remaining sample intensities are read.

- Step 7 Final intensity readings are corrected for background intensities. Polarization or percent intensity values, depending on assay technology, are calculated and converted to the appropriate concentration units.
- Step 8 The assay results are printed.
- Step 9 The paper supply is checked.
- Step 10 The display reads:

**ASSAY COMPLETE**

beeps once, then displays

**READY**

If the carousel is not removed within 5 minutes following the completion of the run, the instrument beeps and displays:

**REMOVE CAROUSEL**

## Calibration Procedure

The TDxFLx<sup>®</sup> System stores a calibration curve for each unit dose assay that is separate and distinct from the calibration curve stored for the random access and batch versions of the same assay. Therefore, prior to running a unit dose assay, the instrument must be calibrated for that assay in the unit dose mode, even if that assay has already been calibrated in the batch or random access modes.

The procedure for unit dose calibration is virtually identical to the batch procedure except that single replicate calibration is allowed. The Cal Reps (assay parameter .6) must be set to 1 when running a single replicate calibration; edit to 2 if duplicate calibration is desired. The unit dose calibration single replicate procedure is as follows:

### System Set-Up

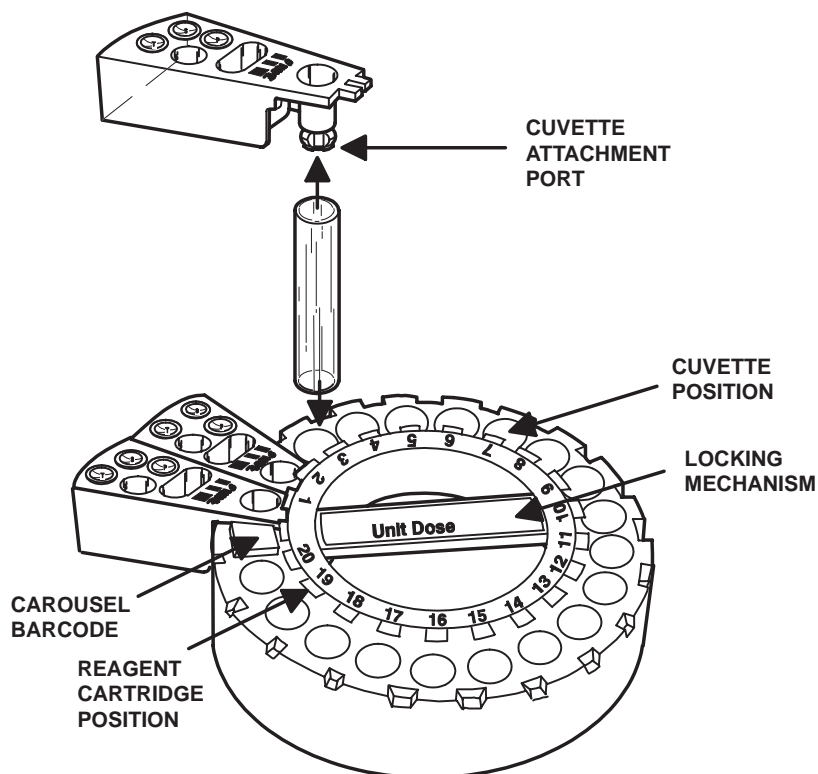
- Ensure that all maintenance has been performed if this is the first run of the shift. Refer to **Section 5.0** for maintenance procedures.
- Program parameter options as desired. Refer to **Programmable Options** in the Introduction section for details.
- Ensure that assay parameter .6 CAL REPS is 1. Press **ASSAY XX.6 DISPLAY**. If 1, press **STOP**, if not, press **EDIT 1 STORE STOP**.

### Preparing the Calibration Carousel

1. Select the unit dose calibration carousel. Before attaching the cuvette to the cartridge, visually inspect the foil seals on the reagent wells of the cartridge for signs of leakage (a flaky white powder around the edges of the foil). Do not use any cartridge that appears to have leaked. Ensure that all disposables are clean and free of foreign matter before use. For more information, contact the **Customer Support Center**.
2. Attach cuvettes to 9 unit dose cartridges for the assay being calibrated. To attach easily and prevent breakage of the cuvette, firmly squeeze the cuvette attachment port on the unit dose cartridge with the thumb and forefinger, and release. Attach the cuvette. Insert the cartridges into Positions 1 through 9.

**NOTE:** For calibration, use only cartridges of the same lot number.

3. Lock the carousel by turning the locking mechanism clockwise until it clicks.



4. Invert the calibrator pack gently five times. Pipette a minimum of 50  $\mu$ L for most assays, (refer to the assays manual for specific sample volume), of calibrator A - F into sample wells of cartridge positions 1 through 6. Avoid splashing, foaming, or bubbling.

Example: Pipette A into Position 1, B into Position 2, etc.

Recap calibrator vials and return pack to proper storage, as described on the labeling.

5. Invert the control pack gently five times. Pipette a minimum of 50  $\mu$ L for most assays, (refer to the assays manual for specific sample volume), of H, M, and L controls into sample wells of cartridge positions 7 through 9. Avoid splashing, foaming, or bubbling. Recap control vials as used and return pack to proper storage, as described on the labeling. Positions 10-20 are available for patient samples. Patient samples must be for the assay being calibrated.
6. Inspect sample wells for bubbles and remove any bubbles with applicator sticks. Use a different stick for each level of calibrator or control.
7. Place the unit dose calibration carousel into the instrument and close the carousel access door.

### Run Calibration

8. Press **RUN**.
9. If the instrument is not programmed to record the operator ID go to step 10. If it is programmed to record this number, the display reads:

OP ID?

Enter your ID number and press **STORE**.

**NOTE:** Reagent lot numbers and patient ID numbers cannot be entered in the unit dose mode.

10. The system reads the barcode on the carousel and then displays:

UNIT DOSE CALIB

The system then reads the barcode on each cartridge to verify the assay being calibrated. Calibration then begins. If the assay name displayed is incorrect, press **STOP** and refer to the **barcode override procedure** in this section.

11. The observed data and the calculated curve prints at the end of the run. Do **NOT** press **STOP** before the printout is complete. This action terminates processing and prevents storage of the calibration curve. When the calibration is completed, the instrument displays:

ASSAY COMPLETE

then,

READY

### Clean-Up

12. Remove the carousel, close the carousel access door, and examine the sample cartridges for evidence of splashing or foaming.

**CAUTION: If splashing or foaming is observed, do not report results. These symptoms indicate a problem and require corrective action. Refer to **Section 6.0** under Observed Problems.**

13. If no splashing or foaming is observed, discard the contents of the carousel. All waste should be disposed of as suitable for patient samples. Refer to **decontamination** and **spill clean-up** in Section 1.0, under Operational Precautions and Limitations.
14. If separation of plastic and glass is not required, unlock the carousel, remove the cartridge, with cuvette attached, and discard into a receptacle.
15. If separation of glass and plastic is required, unlock the carousel and remove the cartridge with cuvette attached. Detach cuvette and discard in glass disposal. Discard the cartridge into its proper receptacle.
16. Verify the calibration acceptability.
17. Edit the CAL REPS back to 2 prior to performing a batch calibration. Press **ASSAY XX.6 EDIT 2 STORE STOP**.

### Calibration Acceptability Criteria (Operator)

The operator verifies acceptability of a calibration curve by three criteria:

1. The PERR (polarization error) values must be within the acceptable range indicated in the assay manual insert.
2. The RMSE (root mean squared error) must be within the acceptable range indicated in the assay manual insert.
3. Each level of control must be within the acceptable ranges indicated in the assay manual insert.

If any of these values are out of range, determine the cause and recalibrate, if necessary. Refer to **Section 6.0 Observed Problems** under Calibration Fails to Meet Specification.

Reading Unit Dose Calibration Printouts

A printout for a unit dose calibration is the same as for the batch calibration printouts except that UNIT DOSE CALIBRATION prints before the date and no reagent lot number is allowed.

UNIT DOSE CALIBRATION				
DATE:				
TIME:				
SERIAL #:				
LOCK= 1				
OP ID #:				
ASSAY: NAPA				
CALIBRATION				
VOL= 2.00				
REPS= 1				
GAIN= 30				
CONC= UG/ML				
I.D.	NET	NET	BLANK	
L	P M	I N	I O	
1 A	236.39	3298.04	467.7	
2 B	206.95	3102.34	418.3	
3 C	170.57	3212.24	413.5	
4 D	146.81	3272.54	478.1	
5 E	131.17	3377.84	420.3	
6 F	112.24	3465.24	478.2	
	P	Q	R	S
I.D.	CONC	AVGP	FITP	PERR
A	0.00	236.39	236.39	0.00
B	2.00	206.95	205.89	1.06
C	6.00	170.57	172.49	-1.92
D	12.00	146.81	145.79	1.02
E	18.00	131.17	130.36	0.81
F	30.00	112.24	112.94	-0.70
RMSE= 0.94				
LOC	SAMPLES			
	CONC	NET P	BLK I	
7	23.97HI	120.23	468.99	U
8	9.62	154.42	418.86	
9	4.49LOW	182.76	435.37	

- A. Unit Dose header
- B. Date of calibration
- C. Time of calibration
- D. Serial number of instrument
- E. Door lock (0 = off, 1 = on)
- F. Operator ID number (optional feature)
- G. Name of assay being calibrated
- H. Volume - final amount of calibrator in cuvette
- I. Number of calibrator replicates
- J. Gain
- K. Concentration units
- L. Position of calibrators in carousel
- M. Net polarization - net intensity readings calculated as a polarization value
- N. Net intensity - fluorescence intensity readings after tracer has been added and correction for background readings made
- O. Blank intensity - calibrator background intensity
- P. Expected concentrations of calibrators
- Q. Average polarization - the average of the net polarizations calculated for each replicated calibrator
- R. Fit polarization - the polarization values obtained when the calibration curve is fitted as close as possible to the average polarizations calculated
- S. Polarization error - calculated as the average polarization (AVGP) for each calibrator minus the fit polarization (FITP) for each calibrator
- T. Root Mean Square Error - a measurement of standard deviation of the PERRs
- U. Concentrations, net polarizations, and blank intensity readings of the control samples

## Assay Procedure

The following paragraphs present the step-by-step procedure for performing a unit dose assay run.

### System Set-Up

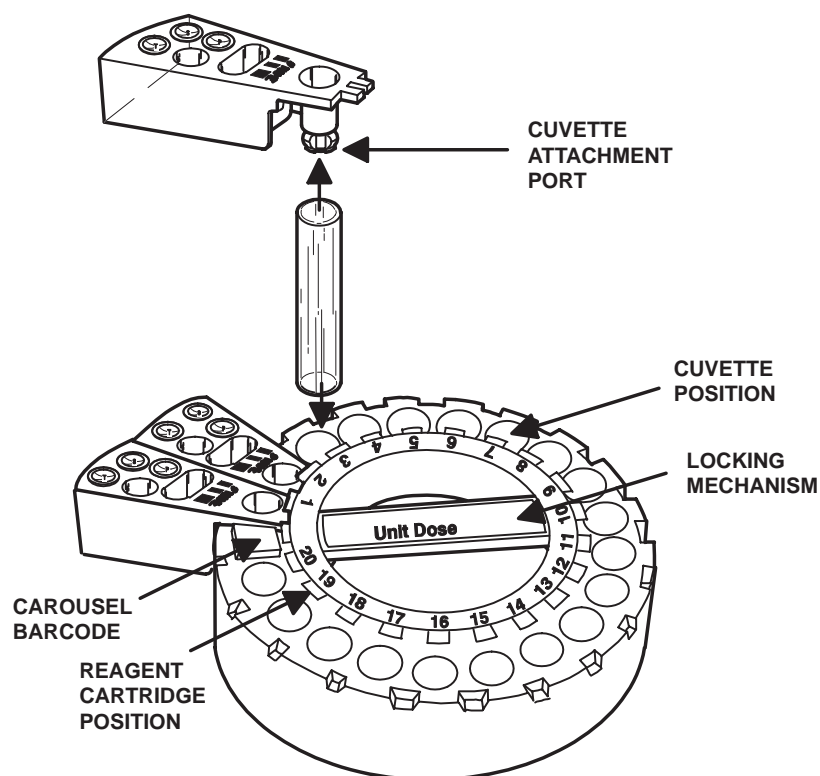
- Ensure that all maintenance has been performed if this is the first run of the shift. Refer to [Section 5.0](#) for maintenance procedures.
- Ensure that a unit dose calibration curve has been stored for each assay being performed. To check the calibration date for a group of assays or a specific assay, press **SYSTEM 4.3 RUN**, enter **1** and press **STORE**. For [FROM ASSAY # \_ \_ ] enter the first or only assay number and press **STORE**. For [TO ASSAY # \_ \_ ] enter the last or only assay number and press **STORE**. The date and time of the calibration(s) print.
- If pretreatment of samples is required, follow the pretreatment procedure described in the appropriate assay section in the assays manual.
- Program parameter options as desired. Refer to [Programmable Options](#) in the Introduction section for details.

### Preparing the Sample Carousel

1. Select the unit dose sample carousel. Before attaching the cuvette to the cartridge, visually inspect the foil seals on the reagent wells of the cartridge for signs of leakage (a flaky white powder around the edges of the foil). Do not use any cartridges that appear to have leaked. Ensure that all disposables are clean and free of foreign matter. For more information, contact the [Customer Support Center](#).
2. Attach a cuvette to a cartridge for each assay being run. To attach easily and prevent breakage of the cuvette, firmly squeeze the cuvette attachment port on the unit dose cartridge with the thumb and forefinger, and release. Push the cuvette attachment port into the cuvette opening. Beginning with Position 1, insert the cartridge into the carousel; be sure not to skip a position on the carousel.



3. Lock the carousel by turning the locking mechanism clockwise until it clicks.



4. Pipette a minimum of 50  $\mu$ L for most assays, (refer to the assays manual for the specific sample volume), of patient sample into cartridge sample wells for each position being used. Avoid splashing, foaming, or bubbling.
5. Inspect the sample wells for bubbles and remove any bubbles with applicator sticks. Use a different applicator stick for each cartridge.
6. After all samples have been pipetted, place the carousel into the instrument and close the access door.

**NOTE:** The Fetal Lung Maturity (FLM) and Ethosuximide unit dose assays must be run separately.

### Run Assays

7. Press **RUN**.
8. If the instrument is not programmed to record the operator ID, go to step 9. If it is programmed to record this number, the display reads:

OP ID?

Enter your ID number and press **STORE**.

**NOTE:** Reagent lot numbers and patient ID numbers cannot be entered in unit dose mode.

9. The system reads the unit dose assay carousel and displays:

UNIT DOSE SPLS

A unit dose header prints. The system reads the barcode on each of the cartridges and displays the assay name for each assay to be performed. As each cartridge barcode is read, the assay name, its position on the carousel, and the calibration date print.

After the assay list is printed, verify that each assay name and its position is correct. The system automatically begins testing after 15 seconds. If an assay name is incorrect, press **STOP** and refer to the **barcode override procedure** in this section.

10. After final readings are taken, assay results for the samples print. The assay is complete when the display reads:

ASSAY COMPLETE

then,

READY

### Clean-Up

11. Remove the carousel, close the access door, and examine the sample cartridges for evidence of splashing or foaming.

**CAUTION: If splashing or foaming is observed, do not report results. These symptoms indicate a problem and require corrective action. Refer to **Section 6.0** under Observed Problems.**

12. If no splashing or foaming is observed, discard the contents of the carousel. All waste should be disposed of as suitable for patient samples. Refer to **decontamination** and **spill clean-up** in Section 1.0 under Operational Precautions and Limitations.
13. If separation of plastic and glass is not required, unlock the carousel, remove the cartridge, with cuvette attached, and discard into a receptacle.
14. If separation of glass and plastic is required, unlock the carousel and remove the cartridge with cuvette attached. Detach cuvette and discard in glass disposal. Discard the cartridge into its proper receptacle.

Reading Unit Dose Assay Printouts

The following printout is typical of a unit dose assay.

<b>A</b>	UNIT DOSE SAMPLES				
<b>B</b>	DATE:				
<b>C</b>	TIME:				
<b>D</b>	SERIAL #:				
<b>E</b>	LOCK= 1				
<b>F</b>	OP ID:				
	ASSAY KEY		<b>H</b>	<b>I</b>	
<b>G</b>	LOC	1	ACETAMINOPHEN	CDATE:	
	LOC	2	ACETAMINOPHEN	CDATE:	
	LOC	3	PROCAINAMIDE	CDATE:	
	LOC	4	PROCAINAMIDE	CDATE:	
	LOC	5	NAPA	CDATE:	
	LOC	6	NAPA	CDATE:	
		<b>J</b>	<b>K</b>		
	1	ACETAMINOPHEN	9.52 LO	UG/ML	
<b>L</b>	NET P:	223.04	<b>M</b> BLK I:	326.84	
	2	ACETAMINOPHEN	20.21 HI	UG/ML	
		NET P:	206.63	BLK I:	425.00
	3	PROCAINAMIDE	9.01	UG/ML	
	4	PROCAINAMIDE	LO	UG/ML	
		NET P:	228.50	BLK I:	410.80
	5	NAPA	9.36	UG/ML	
	6	NAPA	HI	UG/ML	
		NET P:	131.66	BLK I:	415.87

- A. Unit dose header
- B. Date of assay
- C. Time of assay
- D. Serial number of instrument
- E. Door lock (0 = off, 1 = on)
- F. Operator ID number (optional feature)
- G. Location - position in carousel
- H. Name of assay
- I. Date of last calibration stored
- J. Assay name for the corresponding location
- K. Concentration - net polarization converted to concentration units
- L. Net polarization - polarization of sample corrected for background reading (only printed when a HI or LO flag occurs)
- M. Blank intensity - serum background intensity (only printed when a HI or LO flag occurs)

### HI and LOW Readings

The following paragraphs describe the HI and LOW flags that can appear on the printout. Note that NET P and BLK I values are only printed when a flag occurs. More detailed information is provided in [Section 6.0 Troubleshooting](#).

#### HI or LOW Printed After CONC Result

- If any result is outside the programmed therapeutic range (assay parameters .3 and .4), the patient result is flagged as HI or LOW. This alerts the operator to an out-of-range sample. The results should be given special attention and the responsible personnel notified per laboratory procedure.

#### HI or LOW Printed Instead of CONC Result

- If the Net P value is outside the span of the calibration curve, HI or LO prints instead of the numeric result.
- If LO prints, see [Section 6.0 Troubleshooting](#) before proceeding further.
- If LO is repeated after following all troubleshooting, the concentration may be reported as less than the sensitivity of the specific of the specific assay. The sensitivity ranges are provided in the assays manual.
- If HI prints, the test should be rerun using Dilution Protocol. Refer to the [Dilution Protocol](#) procedure in this section. If Dilution Protocol is not allowed for the assay, rerun the test following a manual dilution of the sample. Refer to the assays manual for Dilution Protocol availability for each assay.

**Barcode Override**

There are three types of override procedures for unit dose testing. These are:

- When an individual cartridge is misread and the error code [ERR-STOP-FIX-GO] displays during an assay or calibration run.
- When the barcode reader is not working properly during an assay run.
- When the barcode reader is not working properly during calibration.

**NOTE:** Do not open the door during barcode override as it will trigger the door alarm and abort the barcode override. Refer to the header printout for the barcode fail message of the position in error.

A description of these three procedures follows:

1. Error Code Displayed - Assay Run

**NOTE:** The system allows 15 seconds to begin to correct this error. If step 1 is not started within 15 seconds, the system continues to the next position, and the position causing the error is not assayed.

To override the barcode reader when the message [ERR-STOP-FIX-GO] appears during an assay run:

- a. Press **NEXT**. The display reads:

LOC 1 ASSAY # \_ \_

- b. Check the printout to determine which cartridge is causing the error. BARCODE FAIL prints in the position where the assay name should print.
- c. Press **NEXT** to move to the carousel location that needs to be corrected.
- d. Enter the correct assay number and press **STORE**.
- e. If the error has occurred on subsequent positions, repeat steps c and d.

- f. When all correct assay numbers are entered, press **RUN**. A correct list of assays prints for verification.
- g. When [ASSAY LIST OK?] appears in the display, verify the list is correct and press **STORE** to start the assay run. If the list is not correct, repeat the procedure beginning with **step a**.

**NOTE:** If the **STORE** key is not pressed after verifying the assay list is correct, the assay run does not start. The message [ASSAY LIST OK?] will remain in the display.

## 2. Error Code Displayed - Calibration Run

When any cartridge after the Position 1 cartridge is misread by the barcode reader:

- a. The display reads:

ERR - STOP OR FIX

- b. To continue the run, press **NEXT**. The display reads:

ASSAY # \_ \_

- c. Enter the correct assay number and press **RUN**. Calibration will begin.

## 3. Barcode Failure - Assay Run

When the barcode reader misreads the cartridges during an assay run:

- a. Press **ASSAY “.” RUN**. The display reads:

CALIBRATION?

- b. Press **NEXT**. The display reads:

ENTER ASSAY?

- c. Press **STORE**. The display reads:

LOC 1 ASSAY # \_ \_

- d. Enter the assay number for the cartridge in location 1 and press **STORE**. The display reads:

LOC 2 ASSAY # \_ \_

- e. Repeat step d for **each** position containing a unit dose cartridge. When all assay numbers are entered, press **RUN**.
- f. When [ASSAY LIST OK?] appears in the display, verify the list is correct and press **STORE**.

**NOTE:** In this case of barcode reading failure, the **override procedure** must be performed on each position containing a cartridge.

#### 4. Barcode Failure - Calibration Run

When the barcode reader is not reading properly during calibration:

- a. Press **ASSAY “.” RUN**. The display reads:

CALIBRATION?

- b. Press **STORE**. The display reads:

ASSAY # \_ \_

- c. Enter the number of the assay to be calibrated and press **RUN**. Calibration is performed automatically for the assay number entered.

**NOTE:** During unit dose barcode override, editing can only proceed forward, not backward. Also, once you enter a position, it cannot be cleared without pressing **STOP** and repeating the **barcode override procedure**.



**Introduction**

This section provides a description of **system checks**, **diagnostic tests**, and **additional system verifications** that can be performed on the TDxFLx<sup>®</sup> System.

## System Checks

Eleven system checks are available on the TDxFLx<sup>®</sup> System. To obtain a listing of the checks, press **SYSTEM PRINT**. The following list will be printed.

System 1 - System Status  
System 2 - System Control  
System 3 - System Parameters  
System 4 - Recall Data  
System 5 - Activate Assay  
System 6 - Identification  
System 7 - Thyroid Features  
System 8 - Unit Dose Parameters  
System 9 - Shared-Pack Options  
System 10 - Reagent Carousel  
System 11 - Panels

A description of these systems follows.

### Function Keys

Refer to **Section 1.0 System Description** under Keypad Functions for details on how to display, print, or edit the parameters of the system checks.

### Programmable Options

Refer to **Section 3.0 Operation** under Programmable Options for details on how to edit the different system programmable options.

**System 1 System Status**

This system provides a printout or display of the current status of the following:

- 1.1    DATE            Date currently in memory.
- 1.2    TIME            Time currently in memory.
- 1.3    LIQ C            Current temperature of the liquid heater  
                          (35.0 ± 0.5°C).
- 1.4    PHO C            Current temperature of the optics assembly  
                          (40.2 ± 0.5°C).
- 1.5    AIR C            Current temperature of the air heater (30°C to  
                          37°C, within ± 2°C of Airset **System 2.7**).
- 1.6    REV             Current software version.

**NOTE:** Only System 1.1 and 1.2 can be edited; all other information is status only.

System 2 System Control

System Control directs several functions of the TDxFLx<sup>®</sup> System. Some items are automatically set by the TDxFLx<sup>®</sup> System during special calibration procedures.

- 2.1

BEEP

Controls beeper.  
Instrument beeps when numbers are entered on the keypad and when assay or calibration runs are complete.
- 2.2

LOCK

Controls door lock sensor.
- 2.3

RST SPL

Controls automatic resetting of the sample volume following a dilution protocol assay.  
  
This feature is enabled for all random access assays, most batch mode assays and all Turbo<sup>®</sup> Assays. It is not active for HDL Cholesterol, CRP and unit dose assays.
- 2.4

BAUD

Controls the baud rate for sending printed results to a peripheral device. Available baud rates are 110, 300, 600, 1200, 2400, and 4800.
- 2.5

P BIAS

Polarization bias (P BIAS), a normalization factor for the PMT, corrects for the placement of the polarizer/liquid crystal portion of the optics. System 2.5 is automatically set by the instrument during photo calibration (Test 3.4).
- 2.6

THM OFF

Thermal offset is used to calibrate the cuvette-temperature sensor. System 2.6 is automatically set by the instrument during temperature calibration (Test 3.1).  
  
**CAUTION: Do not edit this parameter unless instructed to do so by the Customer Support Center or Field Service Engineer.**
- 2.7

AIRSET

Airset determines the temperature the instrument maintains at READY.  
  
**CAUTION: Do not edit this parameter unless instructed to do so by the Customer Support Center or Field Service Engineer.**

- |      |         |  |
|------|---------|--|
| 2.8  | PAPER   | This control overrides the paper-out switch in the instrument for the photo check ( <b>Test 2.2</b> ), temperature calibration ( <b>Test 3.1</b> ), and photo calibration ( <b>Test 3.4</b> ). |
| 2.9  | STORAGE | Allows the instrument to store or spool data into memory. Refer to the TDxFLx <sup>®</sup> RS232 Interface Specification manual for instructions on how to use this feature.                   |
| 2.10 | CMP MDE | Activates the serial output mode. Refer to the TDxFLx <sup>®</sup> RS232 Interface Specification manual for instructions on how to use this feature.   |
| 2.11 | CUP SIZ | Dictates the frequency of the <b>CHECK WASTE CUP</b> message. Refer to <b>Section 3.0 Operation</b> , under Programmable Options for instructions on how to edit this feature.                 |

System 3 System Parameters

System parameters define the positions of the stepper motors that move the carousels and the boom arm. Refer to **System 8** for unit dose parameters.

- |      |         |   |
|------|---------|---|
| 3.1  | CAR HM  | Home position for the sample carousel.<br><b>CAUTION: Do not edit this parameter unless instructed to do so by the Customer Support Center.</b>   |
| 3.2  | RBM HM  | Home position for horizontal (R) boom movement.   |
| 3.3  | SERM PT | R-boom step number when the probe is centered over the sample well.   |
| 3.4  | PREDIL  | R-boom step number when the probe is centered over the predilution well.  |
| 3.5  | CUVETTE | R-boom step number when the probe is centered over the cuvette.   |
| 3.6  | POP PT  | R-boom step number when the probe is centered over the “P” vial of a 3-pot reagent pack.  |
| 3.7  | TRA PT  | R-boom step number when the probe is centered over the “T” vial of a 3-pot reagent pack.  |
| 3.8  | ANTI PT | R-boom step number when the probe is centered over the “S” vial of a 3-pot reagent pack.  |
| 3.9  | WASTE   | R-boom step number when the probe is centered over the waste/wash station.  |
| 3.10 | DAC     | Digital to analog converter. The batch barcode reading system uses this value as input to the barcode reading DAC on the analog board.<br><b>CAUTION: Do not edit this parameter unless instructed to do so by the Customer Support Center or Field Service Engineer.</b> |
| 3.11 | RDAC    | Reserved for future use.  |

3.12	CAR RBR	R-boom step number when the boom-arm barcode reader is over the carousel label.
3.13	CAR CBR	Carousel step number when the boom-arm barcode reader is within four to nine steps of detecting the beginning of the sample carousel barcode label.
3.14	ZBM HM	Vertical Z-boom step number when the Z-boom is home.
3.15	4POP PT	R-boom step number when the probe is centered over the “P” vial of a 4-pot reagent pack.
3.16	4TRA PT	R-boom step number when the probe is centered over the “T” vial of a 4-pot reagent pack.
3.17	4ANT PT	R-boom step number when the probe is centered over the “S” vial of a 4-pot reagent pack.
3.18	4WSH PT	R-boom step number when the probe is centered over the “W” vial of a 4-pot reagent pack.

**NOTES:** An **increase** in the current R-boom System 3 parameters (except **System 3.10**) moves the boom arm to the right, and a **decrease** moves the boom arm to the left. An **increase** in System 3.13 moves the sample carousel counterclockwise, and a **decrease** moves the carousel clockwise.

To reposition the probe horizontally, edit the appropriate parameters (**System 3.3** through **3.9** and 3.15 through 3.18).

To reposition the boom-arm barcode reader, edit the appropriate parameter (**System 3.10** or 3.12). Refer to the barcode-reader DAC adjustment check and the boom-arm barcode reader adjustment in **Section 5.0 Maintenance**.

System 4 Recall Data

This system allows the operator to reprint or redisplay data from the most recently run assay or calibration.

**CAUTION:** If System 4.1 or 4.2 options are being used, only the following system parameters can be edited after run is complete:

System 6.7	Abused Drug Printout
System 6.10	Printout Format (Calibration runs will be formatted by location only.),
System 6.11	Date Format
System 6.12	Reagent Pack Usage

Before reprinting or redisplaying information, do not edit any other parameters or initiate a run (assay, calibration, or diagnostic test) after the original run is complete.

4.1 REPRINT DATA

To reprint data for assay or calibration run:

Press **SYSTEM 4.1 RUN**.

The date and time are indicated as REPRINT DATE and REPRINT TIME, respectively. A line indicating REPRINTED DATA then prints. The remainder of the information prints exactly as the original. If no data is available to print, the display shows

NO DATA AVAIL

In a unit dose run, a unit dose header prints before REPRINT DATE.

4.2 DISPLAY DATA

To display data for an assay run:

1. Press **SYSTEM 4.2 RUN**. The assay name displays.
2. Press **NEXT**. The specific sample carousel position and concentration value are displayed. If applicable, the specified concentration is flagged HI or LOW.
3. Press **NEXT**. The specific sample carousel position and blank intensity value are displayed. The specific blank intensity is flagged HI if applicable.



4. Repeat **Steps 2 and 3** until all results are displayed for each sample carousel position.
  - If a sample was not pipetted, the appropriate error code displays.
  - After the last result displays, the instrument returns to:

READY

To display data for a calibration run:

1. Press **SYSTEM 4.2 RUN**. The assay name displays.
2. Press **NEXT**. The specific sample carousel position and net polarization value are displayed as:

P =

3. Press **NEXT**. The specific sample carousel position and net intensity value are displayed as:

N =

4. Press **NEXT**. The specific carousel position and blank intensity are displayed as:

B =

5. Repeat Steps 2 through 4 until all raw data is displayed on each carousel position. If the criteria for acceptability are not met, an appropriate error message is displayed. Refer to **Section 6.0 Troubleshooting** for corrective action.

6. If all data is acceptable, the PERR or ERR for each calibrator displays with the calibrator letter each time **NEXT** is pressed. When all PERR or ERR values have been displayed, the RMSE will be displayed. If a sample is not pipetted, only the carousel position is displayed. After the RMSE value is displayed, then the instrument returns to:

READY

**NOTES:** No patient samples or controls are displayed on a calibration run.

Patient IDs are not displayed on an assay run.

When displaying calibration data from an REA assay, only the initial intensities (Initial V) are displayed. The final intensities (Final V) are not displayed.

#### 4.3 RECALL CAL DATES

To recall calibration date and time for a specific assay or group of assays:

1. Press **SYSTEM 4.3 RUN** [0=BA 1=UD 2=RA \_\_ ] displays.
2. Press 0 for batch, 1 for unit dose or 2 for random access, and press **STORE**.
3. The display reads [FROM ASSAY # \_\_ \_\_ ]. To recall calibration dates for a group of assays, enter the first two-digit assay number and press **STORE**.
4. The display reads [TO ASSAY # \_\_ \_\_ ]. To recall calibration dates for a group of assays, enter the last two-digit assay number and press **STORE**. To recall the calibration date for one assay, reenter the same number as in Step 3 and press **STORE** (e.g., FROM 01 to 10 or FROM 30 to 30).
5. Calibration date(s) and time(s) are printed.

#### 4.4 REAGENT TABULATN

The purpose of this report is to provide the operator with a historical list of the reagents (batch and random access) used to date on the analyzer.

1. Press **SYSTEM 4.4 RUN**. The display reads [FROM ASSAY # \_\_ \_\_ ].
2. Enter the starting assay number and press **STORE**.
3. The display reads [TO ASSAY # \_\_ \_\_ ]. To print a report for a group of reagents, enter the last two-digit assay number and press **STORE**. To print for one reagent only, reenter the same number as in Step 2 and press **STORE**. To abort or stop the printout at any time, press **STOP**.

4. A tabulation report is printed as shown below. This report shows the following information:
- A. Assay number
  - B. Reagent pack 13-digit barcode number
  - C. Reagent lot number
  - D. Number of tests used
  - E. Date reagent pack was first initialized into the system
  - F. Reagent expiration date (if available)

TDxFLx REAGENTS TABULATION REPORT DATE: SERIAL #: DATABASE LAST INITIALIZED				
	ASSAY NUMBER	BARCODE NUMBER	TESTS USED	INIT DATE
A	1	4941700036439	0	XX/XX/XX
B		LOT 123456789	EXP	XX/XX
C	1	4280412502925	0	XX/XX/XX
		LOT 123456789	EXP	XX/XX
	1	0145745459349	0	XX/XX/XX
		LOT 123456789	EXP	XX/XX
	1	0057097709420	0	XX/XX/XX
		LOT 123654789	EXP	XX/XX
	2	7422133607223	0	XX/XX/XX
		LOT 123654789	EXP	XX/XX
	4	9211796311233	0	XX/XX/XX
		LOT 147852369	EXP	XX/XX
	4	9333324107231	0	XX/XX/XX
		LOT 123456789	EXP	XX/XX
	4	2172433992179	0	XX/XX/XX
		LOT 123456789	EXP	XX/XX
	4	0305089942320	28	XX/XX/XX
		LOT 123456789	EXP	XX/XX
	4	9870453343027	28	XX/XX/XX
		LOT 123456789	EXP	XX/XX
	5	4069126647711	0	XX/XX/XX
		LOT 123698574	EXP	XX/XX
	5	2233433052584	0	XX/XX/XX
		LOT 987456321	EXP	XX/XX

### System 5 Activate Assay

This system allows the operator to activate parameters for new assays and for changes in reagent antibody pools.

#### 5.1 ACTIVATE ASSAY

To activate an assay requiring one activation code:

1. Press **SYSTEM 5.1 RUN**. [ASSAY NUMBER \_\_ \_\_] displays.
2. Enter the appropriate two-digit assay number (e.g., enter assay number 7 as 07).
3. Press **STORE**. The display shows [#=] followed by 14 blanks.
4. Enter the 14-digit activation code obtained from the kit enclosure or through the **Customer Support Center**. If an error is made during entry of the code, press **CLEAR** to erase the last digit entered.
5. When the code is entered correctly, press **STORE**. [ASSAY ACTIVATED] and then [READY] displays.
6. Press **ASSAY XX PRINT** (using the appropriate two-digit assay number) to obtain a printout of the assay parameters after activation. Verify that these agree with the parameters given in the kit enclosure or through the **Customer Support Center**. Edit any parameters to the correct values if necessary.
7. Calibrate the newly activated assay prior to an assay run.

#### 5.2 U.D. QC PARAMS

To activate a new assay with multiple activation codes:

**NOTE:** This feature applies only to the unit dose mode of operation.

1. Follow Steps 1 through 5 of the activation procedure for one activation code (System 5.1).
2. Press **SYSTEM 5.2 RUN** [UD ASSAY # \_\_ \_\_] displays.

3. Enter the appropriate two-digit assay number.
4. Press **STORE**. The display shows

#1 = \_ \_ \_ \_ \_

5. Enter the first 13-digit activation code obtained from the kit enclosure or through the **Customer Support Center**.

**NOTE:** If an error is made during entry of a code, press **CLEAR** to erase the code and reenter all 13 digits.

6. When the code is entered correctly, press **STORE**. The display shows [#2=] followed by 13 blanks.
7. Enter the second 13-digit activation code obtained from the kit enclosure or through the **Customer Support Center**.
8. When the code is entered correctly, press **STORE**. The display shows [#3=] followed by 13 blanks.
9. Enter the third 13-digit activation code obtained from the kit enclosure or through the **Customer Support Center**.
10. When the code is entered correctly, press **STORE**. [ASSAY ACTIVATED] and then [READY] will be displayed.
11. Press **ASSAY XX PRINT** (using the appropriate two-digit assay number) to obtain a printout of the assay parameters after activation. Verify that these agree with the parameters from the kit enclosure or through the **Customer Support Center**. Edit parameters to the correct values as necessary.
12. Calibrate the newly activated assay prior to an assay run.

### System 6 Identification

This system allows the operator to place identifying information on the printout or to request categorical information about the assays that are available or under development.

- |     |                  |  |
|-----|------------------|--|
| 6.1 | SERIAL #         | The five-digit serial number of your TDxFLx <sup>®</sup> System is stored at factory set. Any attempt to edit this parameter results in the message [WRT PROTECT].   |
| 6.2 | ASSAY CATEGORIES | This option allows the operator to obtain a list by assay categories of all assays currently available and under development. To obtain this list, press <b>SYSTEM 6.2 RUN</b> .   |
| 6.3 | OP ID #          | This feature allows the operator to enter an operator ID (up to nine digits).  |
| 6.4 | PBR #            | Not active.  |
| 6.5 | RGT LOT          | In the random access or batch modes, this feature controls the inclusion or exclusion of reagent lot numbers on the reagent load list printout or the assay header printout. This feature is not activated for unit dose or Turbo <sup>®</sup> Assays. |
| 6.6 | PAT ID           | This feature allows the operator to enter a patient ID (up to ten digits) for each patient sample on a sample carousel. This feature is not activated for unit dose assays.  |
| 6.7 | T PRINT          | Controls the type of printout for abused drug assays only. For more details on this option refer to <b>Section 3.0 Operation</b> under <b>Batch Calibration</b> and <b>Assay Procedures</b> .  |

6.8	TOT T3	Not active.								
6.9	EXP DATE	<p>This feature controls the inclusion or exclusion of the reagent pack expiration date in the reagent load list printout.</p> <p>If the feature is on (1 = On), the expiration date of each reagent pack to be used is printed.</p> <p>If the feature is off (0 = Off), the expiration date is not printed.</p> <p>The expiration date is printed as it is embedded in the barcode label. If it is not embedded, then the expiration date will not be printed regardless of whether this parameter is turned on.</p>								
6.10	COLLATE	<p>This feature allows three printout format options:</p> <table><tr><th>Options</th><th>Printout Format</th></tr><tr><td>0</td><td>By location</td></tr><tr><td>1</td><td>By patient ID (all results for one patient printed together)</td></tr><tr><td>2</td><td>By assay (all results for one assay printed together)</td></tr></table>	Options	Printout Format	0	By location	1	By patient ID (all results for one patient printed together)	2	By assay (all results for one assay printed together)
Options	Printout Format									
0	By location									
1	By patient ID (all results for one patient printed together)									
2	By assay (all results for one assay printed together)									
6.11	DTE FMT	<p>This feature allows the operator to choose a different date format. The selections available are:</p> <table><tr><th>Options</th><th>Display Format</th></tr><tr><td>0</td><td>MM/DD/YY</td></tr><tr><td>1</td><td>DD/MM/YY</td></tr><tr><td>2</td><td>YY/MM/DD</td></tr></table>	Options	Display Format	0	MM/DD/YY	1	DD/MM/YY	2	YY/MM/DD
Options	Display Format									
0	MM/DD/YY									
1	DD/MM/YY									
2	YY/MM/DD									
6.12	TST CNT	This feature allows the option to print the number of tests used or number of tests left for a reagent pack.								
6.13	LOADLIST	This feature allows the option to print or not print the reagent loadlist for random access testing.								
6.14	SPL LST	This feature allows the option to print or not print the sample loadlist at the beginning of a run.								



**System 7 Thyroid Feature**

Refer to the T-Uptake assay insert in the assays manual for complete instructions regarding this feature.

System 8 Unit Dose Parameters

This system defines additional positions and actions for the carousel and boom-arm stepper motors when the system is in the unit dose mode. These parameters, in conjunction with the applicable **System 3** parameters, direct the positions of the boom arm and the carousel during specific steps of a unit dose assay or calibration run.

8.1	UD RBM	R-boom step number when the boom-arm barcode reader is over the unit dose cartridge barcode label.
8.2	UD CAR	Carousel shift (from tab*) to position the boom-arm barcode reader within seven steps of detecting the transition from white to black on the unit dose cartridge barcode label.
8.3	UD POP	R-boom step number when the probe is centered over the “P” well on the unit dose cartridge.
8.4	UD TRA	R-boom step number when the probe is centered over the “T” well on the unit dose cartridge.
8.5	UD ANTI	R-boom step number when the probe is centered over the “S” well on the unit dose cartridge.
8.6	UD SH A	Carousel shift (from tab*) to position the probe over the center of the “S” well on the unit dose cartridge.
8.7	UD SH P	Carousel shift (from tab*) to position the probe over the center of the “P” well on the unit dose cartridge.
8.8	UD PUNC	The number of steps the Z-boom will move down after first sensing foil on initial puncture. After moving down the number of steps specified in System 8.8, the Z-boom pauses for the period of time specified by <b>System 8.9</b> .
*	Tab =	One of 21 positions (20 cartridge positions ± 1 carousel barcode label position)

- 8.9 UD WAIT The length of time for the pause in Z-boom motion after the initial puncture of foil and drop of the number of steps specified in **System 8.8**. This time is expressed as the number of 1/600 seconds. If System 8.9 is 300, then the pause will be 300/600 or 1/2 second. After the pause, the Z-boom moves down to allow the probe to find and pipette reagent.
- 8.10 UD R B Liquid-level low trip point for the unit dose cartridge reagent wells. If the Z-boom has to drop this far to find reagent, there is too little reagent to perform the assay. A **LIQUID LEVEL LO** message is printed instead of results for this position on the carousel.

**Systems 8.1 through 8.5** are automatically set during the **Unit Dose Boom Calibration (Test 3.6)**. They can also be determined manually by hand control capabilities of the TDxFLx<sup>®</sup> System and then edited by using the keyboard. These parameters are specific to a given instrument.

**Systems 8.6 through 8.10** are the same for all instruments.

**CAUTION:** Do not edit these parameters unless instructed to do so by the **Customer Support Center** or Field Service Engineer.

### System 9 Shared Pack Options

This system parameter allows optional sharing of reagent packs. Refer to **Section 3.0 Operation** under Programmable Options for detailed instructions on how to edit this system parameter.

### System 10 Reagent Carousel

This system defines the positions of the stepper motors that move the reagent carousel and the boom arm.

- |      |          |  |
|------|----------|--|
| 10.1 | RCRSL HM | Home position for reagent carousel.  |
|      |          | <b>CAUTION: Do not edit this parameter unless instructed to do so by the Customer Support Center.</b>                                  |
| 10.2 | WPOP RBM | R-boom step number when the probe is centered over the “P” vial. This parameter should be the same as that of 10.4 WANT RBM.           |
| 10.3 | WTRA RBM | R-boom step number when the probe is centered over the “T” vial.   |
| 10.4 | WANT RBM | R-boom step number when the probe is centered over the “S” vial. This parameter should be the same as that of parameter 10.2 WPOP RBM. |
| 10.5 | WDG BRCD | Reagent carousel step number where the reagent barcode reader begins reading wedges.   |
| 10.6 | WSTE ZBM | Z-boom step number when the probe is over the waste/wash station.  |
|      |          | <b>CAUTION: Do not edit this parameter unless instructed to do so by the Customer Support Center.</b>                                  |
| 10.7 | RGNT ZBM | Z-boom home for the reagent carousel.  |
|      |          | <b>CAUTION: Do not edit this parameter unless instructed to do so by the Customer Support Center.</b>                                  |

**System 11 Panels**

This system defines panel assay information. Reference **Section 3.0 Operation** for information on programming and testing panels.

## Diagnostic Tests

The TDxFLx<sup>®</sup> System is self-diagnostic for many major components. To obtain a listing of the various types of diagnostic tests in the instrument, press **TEST PRINT**. A list of the following diagnostic tests prints:

Test 1 - Maintenance

Test 2 - Specification Checks

Test 3 - Calibration

Test 4 - Hand Controls

Test 5 - Board Tests

Test 6 - Special Tests

A description of these tests follows.

### Function Keys

Refer to **Section 1.0 System Description** under Keypad Functions for details on how to display, print, or edit the parameters of the diagnostic tests.

**Test 1 Maintenance**

All maintenance diagnostic tests are used by the manufacturer to verify system operation and should not be used by the operator.



### Test 2 Specification Checks

Specification checks test instrument subsystems independent of the chemistries. These checks are used to verify instrument operation during installation and as part of the routine maintenance program for the instrument. To obtain a listing of the specification checks, press **TEST 2 PRINT**. The following options print:

- Test 2.1      - TEMP CHECK
- Test 2.2      - PHOTO CHECK
  - 2.2.1      - GAIN
- Test 2.3      - PIPE CHECK

#### Test 2.1 - Temp Check

This test checks the operation of all temperature control circuitry by measuring the temperatures of the three heating systems (air, optics, and liquid) during various test operations.

This test is performed upon installation and routinely as a monthly maintenance procedure. Directions for performing the temperature check procedure are found in [Section 5.0 Monthly Maintenance](#).

#### Test 2.2 - Photo Check

The photo check diagnostic test checks the optical system specifications. The procedure helps to ensure photometer/optical system reproducibility.

This test is performed upon installation and routinely as a weekly maintenance procedure. Directions for performing a photo check procedure are found in [Section 5.0 Weekly Maintenance](#).

#### Test 2.3 - Pipe Check

This test is used to check the system's ability to perform linear pipetting, independent of the chemistries.

This test is performed upon installation and as a monthly maintenance procedure. Directions for performing pipe check procedure can be found in [Section 5.0 Monthly Maintenance](#).

### Test 3 Calibration

These tests provide automatic calibration of several subsystems of the TDxFLx<sup>®</sup> System. To obtain a listing of the calibration tests available, press **TEST 3 PRINT**. The following options will be printed:

- Test 3.1 - TEMP CAL
- Test 3.2 - BOOM CAL
  - 3.2.1 - RPK ST
  - 3.2.2 - RPK P
  - 3.2.3 - PRD CUP
  - 3.2.4 - PRD SRM
  - 3.2.5 - CAR STR
  - 3.2.6 - CAR STC
- Test 3.3 - CRSL CAL
- Test 3.4 - PHOTO CAL
  - 3.4.1 - GAIN
  - 3.4.2 - INTENS
  - 3.4.3 - HV COEF
  - 3.4.4 - POL
- Test 3.5 - ZBOOM CAL
- Test 3.6 - U.D. BOOM CAL
- Test 3.7 - 4 POT-BOOM CAL
- Test 3.8 - TURBO CRSL CALIB
- Test 3.9 -
- Test 3.10 - AUTO BOOM CAL
- Test 3.11 - TEST NOT DEFINED
- Test 3.12 - RESET POINTERS
- Test 3.13 - RGT CRSL CAL
- Test 3.14 - BUFFER RUN
- Test 3.15 - BATCH BUFFER RUN

### Test 3.1 - Temperature Calibration

This procedure is used to recalibrate **System 2.6** (THM OFF) when the cuvette temperature with liquid is out of specification during TEMP CHECK (**Test 2.1**).

**NOTE:** This procedure should not be performed unless requested by the **Customer Support Center**.

### Materials Needed

- Sample or calibration carousel
- 3 cuvettes
- External temperature probe accurate to  $\pm 0.1^{\circ}\text{C}$ . Abbott Laboratories Digital Thermometer LN 9520-37 or equivalent.

### Procedure

1. Insert empty cuvettes into Positions 9, 10 and 11. Lock the cuvettes into position.
2. Place the carousel into the instrument. Leave the door open.
3. Press **TEST 3.1 RUN**. The display reads [TEMP CAL]. Two milliliters of buffer is dispensed into the three cuvettes.
4. Warm the external temperature probe to approximately  $34^{\circ}\text{C}$  (hold tightly in your hand).
5. When the display changes to [INSERT PROBE], insert the prewarmed temperature probe into the cuvette in Position 10.
6. Press **STORE**. The display reads [TEMP SETTLE]. This message remains for several seconds while the temperature probe is equilibrating.
7. When the display changes to [ENTER DEG C \_\_ \_\_ . \_\_] and the temperature on the monitor is within range, enter the reading of the temperature probe to the nearest tenth of a degree.

The temperature on the monitor should read from  $33.5^{\circ}\text{C}$  to  $34.5^{\circ}\text{C}$ . (If an incorrect entry is made, press **CLEAR** and enter the correct temperature. When the temperature has been entered correctly, press **STORE**. Remove the temperature probe from the cuvette immediately. If the temperature is out of range, press **STOP** and contact the **Customer Support Center** for additional instructions. Assays can be run while you are waiting to correct a temperature problem if QC is within specifications.)

**System 2.6** THM OFF is calculated and stored into memory. The display flashes [CALIB COMPLETE] and then [READY].

### Test 3.2 - Boom Calibration

This diagnostic test determines and stores in memory the correct positions for the movement of the boom and the carousel (**Systems 3.3** through **3.9** and **3.12** through **3.14**). This procedure, as follows, is for the batch mode of operation. Refer to **Test 3.6** for the unit dose boom calibration, and **Test 3.13** for the reagent carousel calibration.

### Materials Needed

- Calibration carousel
- 5 sample cartridges
- 1 cuvette
- 50 µL pipet
- X SYSTEMS® Dilution Buffer
- Batch-pack adapter
- 3-pot reagent pack

### Procedure

1. Place sample cartridges in Positions 1, 5, 10, 15, and 20. Place the cuvette in Position 1. Lock the cuvette into position.
2. Accurately pipette 50 µL of X SYSTEMS® Dilution Buffer into the sample well of each cartridge. Pipette the fluid volume directly into the bottom of the sample wells.
3. Install the **batch-pack adapter**.
4. Remove the vial caps from a 3-pot reagent pack, and place the pack on the **batch-pack adapter**.
5. Place the carousel into the instrument. Leave the access door open.
6. Press **TEST 3.2 RUN**. The display reads [BOOM CAL]. The boom and carousel perform these movements:
  - a. Boom seeks home.
  - b. Carousel rotates.
  - c. Barcode reader finds the edge of the carousel label holder (**System 3.12**).
  - d. Carousel rotates.
  - e. Barcode reader locates carousel barcode (**System 3.13**).
  - f. Carousel rotates.
  - g. Boom moves home.

7. After the instrument determines the correct barcode positions, the probe moves to these positions to allow the operator to adjust the probe to center:
  - a. “P” vial (System 3.6)
  - b. “T” vial (System 3.7)
  - c. “S” vial (System 3.8)
  - d. Waste/wash station (System 3.9)
  - e. Sample well (System 3.3)
  - f. Dilution well (System 3.4)
  - g. Cuvette (System 3.5)

When the display shows [ADJUST POSITION], press **0** to move the boom arm left or “.” to move the boom arm to the right. Press **STORE** when the correct boom position has been determined. The boom moves to the next position.

When **STORE** is pressed while the probe is in the sample well and the dilution well positions, the probe moves further down into the well. This action allows a more accurate adjustment. When **STORE** is pressed the second time, the boom moves to the next position.

8. The probe then dips into each of the five sample wells to determine the correct Z-boom position for the liquid-level sensors.

The display shows [Z-BOOM LEVEL = XXX], where XXX is the step number where liquid was detected. This step number should be 172 or 173.

Press **NEXT** to check all five carousel positions. Record the step number at each position.

The step numbers must not vary by more than one step. Remove cartridges and repipette any outliers before continuing. Reread all five positions by pressing **NEXT**. Return to the carousel position that had the lowest step number and adjust it to 172 as follows:

- a. To increase the step number, press **0**.
- b. To decrease the step number, press “.”.
- c. When the display shows 172 with the probe down in the cup, check all other positions by pressing **NEXT**. To recheck a single position, press **CLEAR**.

**NOTES:** The Z-boom position step number for one position cannot be changed without affecting the other position’s numbers.

In any position where fluid is not detected at a step number of 173 or less, the sample will be skipped during an assay or calibration run.

- d. Verify that no position shows a step number greater than 173, then press **STORE**.

9. When the correct Z-boom home value (**System 3.14**) is stored in memory, the display returns to [READY].
10. Press **SYSTEM 3 PRINT** to obtain a printout of the new **System 3.3** through **3.9** and **3.12** through **3.14** parameters.

**NOTE:** The boom and carousel positions stored during this procedure cannot be verified by running another boom calibration, doing so would recalibrate rather than verify. To check these positions, perform a **buffer run** or use the **Test 4 hand controls**.

#### Test 3.3 - Carousel Calibration

This test calibrates the carousel home (**SYSTEM 3.1 CAR HM**) position and ensures that the carousel is centered correctly in the photometer read station when intensity measurements are made. This procedure requires a carousel home alignment tool (not supplied with the TDxFLx<sup>®</sup> System).

**DO NOT** edit the **System 3.1** parameter. This calibration is done by an Abbott Field Service Engineer.

#### Test 3.4 - Photo Calibration

Contact the **Customer Support Center** **before** performing this procedure.

Photo calibration is used to calibrate the photomultiplier tube by calculating the correct high-voltage coefficient (**Test 3.4.3**) and P BIAS values (**System 2.5**). Performing a photo calibration may be necessary after a photo check (**Test 2.2**) failure.

#### Materials Needed

- X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel

#### Procedure

1. Locate the label along the side of the inner wall of the carousel. This label lists the gain, intensity, and polarization values for that particular carousel.
2. Press **TEST 3.4 PRINT** and **TEST 2.2 PRINT**.
3. Check the gain, intensity, and polarization parameters on the printout with those marked on the carousel label. Verify that the **GAIN in Test 2.2.1** agrees with the carousel label.

4. If any of the values do not match, press **TEST 3.4.X EDIT** and/or **TEST 2.2.1 EDIT** (enter the number from the carousel) **STORE STOP**.
5. Print out the new values and ensure that the parameters match those on the carousel.
6. Place the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set carousel into the instrument. Close the access door
7. Press **TEST 3.4 RUN**. The date, time, and serial number for the instrument are printed. If the boom-arm barcode reader is unable to read the carousel label or if the carousel is not a valid X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set carousel, the display reads [**CAR LBL ERR-RUN?**].

Press **STOP** if you do not wish to continue. Otherwise, press **RUN**. The display reads [PHO CAL].

The calibration routine requires from 10 to 30 minutes. When the calibration is completed, the high-voltage coefficient and P-BIAS values followed by PASS are printed. The new high-voltage coefficient and P-BIAS values have been stored in permanent memory.

The instrument returns to [READY].

If the test does not pass, an error message is displayed and printed. The test should be repeated. Refer to [Section 6.0 Troubleshooting](#) for assistance.

8. When the test passes, run a photo check procedure ([Test 2.2](#)). Use the same X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel for the Photo Check procedure that was used for the Photo Calibration. The operator may designate the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel(s) for use with specific instrument serial number(s) by placing a serial number label on the inner ring opposite the factory-installed carousel label. See [Section 5.0 Maintenance](#) under Weekly Maintenance. Photo check values should fall within these ranges:

Average Intensity  $\pm 12\%$  of the carousel labeled value

Intensity Range  $\leq 600$

Average Polarization  $\pm 1.5$  mP of carousel labeled value

Polarization Range  $\leq 2.5$  mP

If the photo check does not meet these specifications, rerun the photo calibration and photo check procedures. If the values are still out of range, contact the [Customer Support Center](#).

### Test 3.5 - Z-Boom Calibration

Z-boom calibration determines the correct liquid-level sensing position for the Z-boom (**SYSTEM 3.14 ZBM HM**) only, and automatically stores this position in memory.

#### Materials Needed

- Sample or calibration carousel
- 5 sample cartridges
- 50  $\mu$ L pipet
- X SYSTEMS<sup>®</sup> Dilution Buffer

#### Procedure

1. Place sample cartridges in Positions 1, 5, 10, 15, and 20 of a sample or calibration carousel.
2. Accurately pipette 50  $\mu$ L of X SYSTEMS<sup>®</sup> Dilution Buffer into the sample well of each cartridge. The fluid volume must be pipetted directly into the bottom of the sample well.
3. Place the carousel into the instrument. Leave the access door open.
4. Press **TEST 3.5 RUN**. The display reads [Z-BOOM CAL]. The probe then dips into each of the five sample wells to determine the correct Z-boom position for the liquid-level sensor.

The carousel returns to Position 1, and the display reads [Z-BOOM LEVEL = XXX], where XXX is the step number of the Z-boom where liquid was detected. This step number should be 172 or 173.

Check all five carousel positions by pressing **NEXT**. Record the step number at each position.

The step numbers must not vary by more than one step. Remove cartridge(s) and repipette any outliers before continuing. Press **NEXT** to reread all five positions. Return to the carousel position that had the lowest step number and adjust it to step 172 as follows:

- a. To increase the step number, press **0**.
- b. To decrease the step number, press **“.”**.
- c. When the display shows step 172 with the probe down in the cup, check all other positions by pressing **NEXT**. To recheck a single position press **CLEAR**.

**NOTES:** The step number for one position cannot be changed without affecting the other positions' numbers.

In any position where fluid is not detected at a step number of 173 or less, the sample is skipped during an assay or calibration run.

- d. Verify that no position shows a number greater than 173, then press **STORE**.



5. The new Z-boom value is stored in memory and the display reads [READY].
6. Press **SYSTEM 3 PRINT** to obtain a printout of the parameters. The **3.14 ZBM HM** (vertical boom home) parameter will have been calibrated.

### Test 3.6 - Unit Dose Boom Calibration

The unit dose boom calibration (Test 3.6) must be performed after changing the probe.

**NOTE:** The unit dose boom calibration should be performed only after a boom calibration (**Test 3.2**) has been performed.

### Materials Needed

- 1 unit dose cartridge
- 1 cuvette
- Unit dose calibration carousel
- 50  $\mu$ L pipet
- X SYSTEMS<sup>®</sup> Dilution Buffer

### Procedure

1. Insert a unit dose cartridge with a cuvette attached into Position 1 of a unit dose calibration carousel. Lock the cartridge into position.
2. Pipette a minimum of 50  $\mu$ L of X SYSTEMS<sup>®</sup> Dilution Buffer into the sample well of the unit dose cartridge.
3. Place the carousel into the instrument. Leave the access door open.
4. Press **TEST 3.6 RUN**. The display reads [U.D. CAL CAROUSEL] if you are using a unit dose calibration carousel or [U.D. CAROUSEL] if you are using a unit dose sample carousel.

**NOTE:** If a [**BARCODE FAIL**] occurs and you want to continue the boom calibration using this carousel, press **NEXT**. The messages [CK CAROUSEL READ] and [CONTINUE?] appear. Press **STORE**. The calibration continues with Step 5.

5. When [SYS 3 PARAMS OK?] appears in the display, the system is asking if a boom calibration has been performed in the batch mode of operation. If the boom calibration has been done, press **STORE**. [U.D. BOOM CAL] displays. The carousel rotates and stops, then the probe is positioned over the cuvette.

**NOTE:** If a batch mode boom calibration has not been performed, press **STOP** and perform the batch mode boom calibration (**Test 3.2**).

6. When [ADJUST POSITION] appears in the display, center the probe in the cuvette position. Press “.” to move the boom arm one step to the right. Press **0** to move the boom arm one step to the left. Press **STORE** when the probe is centered in the cuvette position.
7. The probe moves further down into the cuvette. If further adjustment is required to center the probe, press the “.” key to move the probe to the right and the **0** key to move it to the left. Press **STORE** when the probe is centered.
8. The probe then moves to the “T” well. Use keys “.” and **0** to center the probe over the well. Press **STORE** when the probe is centered. [U.D. BARCODE ] displays.
9. The boom-arm barcode reader locates and reads the barcode on the unit dose cartridge. When the assay name is displayed, press **STORE** if the name is correct.

If the assay name displayed is incorrect, perform the following steps:

- a. Press **PRIME** to turn the boom-arm barcode reader lights on.
- b. Press **0** to move the boom-arm barcode reader left or “.” to move it right, as needed, to center the barcode reader over the unit dose cartridge barcode.
- c. Press **6** to move the carousel clockwise or **3** to move it counterclockwise until the brighter of the two barcode reader lights is approximately 1/8 of an inch before the cartridge barcode label.
- d. When the boom-arm barcode reader lights are properly centered in front of the cartridge barcode label, press **DISPLAY** three times to read the present cartridge barcode label three times. If the assay name displays all three times correctly, press **STORE**. (If the assay name displayed is not correct, call the **Customer Support Center**.)

**NOTE:** At this point, the unit dose boom calibration is complete and the display reads [READY].

10. Press **SYSTEM 8 PRINT** and **SYSTEM 3 PRINT** to obtain printouts of the parameters. Keep a copy of these printouts for future reference.

Test 3.7 - 4-Pot Reagent Pack Boom Calibration

The 4-pot reagent pack boom calibration (Test 3.7) must be performed:

- before the initial assay run of any 4-pot reagent pack assays
- whenever a boom calibration (Test 3.2) is performed.

**NOTE:** The 4-pot reagent pack boom calibration should be performed only after a boom calibration (Test 3.2) has been performed.

Materials Needed

- Batch-pack adapter
- 4-pot reagent pack

Procedure

1. Install the batch-pack adapter.
2. Remove the vial caps and insert a 4-pot reagent pack into the instrument. Leave the carousel access door open.
3. Press **TEST 3.7 RUN**. The display reads [4-POT - BOOM CAL].
4. When [ADJUST POSITION] appears in the display, center the probe over the “P” vial. Press “.” to move the boom arm one step to the right. Press **0** to move the boom arm one step to the left. Press **STORE** when the probe is centered over the “P” vial.
5. Repeat this process (Step 4) for the “T”, “S”, and “W” vials.
6. After the new R-boom values for **SYSTEM 3.15**, **3.16**, **3.17**, and **3.18** are stored in memory, the display reads [READY].
7. Press **SYSTEM 3 PRINT** to obtain a printout of the parameters.

### Test 3.8 - Turbo<sup>®</sup> Carousel Calibration

This diagnostic test is used for Turbo<sup>®</sup> Specific Protein assays. Refer to the TDxFLx<sup>®</sup> & TDx<sup>®</sup> Turbo<sup>®</sup> Operation Supplement for the procedure.

### Test 3.9 - Reserved for Future Applications

### Test 3.10 - Automated Probe Positioning and Boom Calibration

This diagnostic test determines and stores the correct positions for the movement of the boom and carousel. This procedure is for the batch mode of operation.

#### Materials Needed

- Batch-pack adapter
- Calibration carousel
- Probe-positioning cartridge
- 3-pot reagent pack
- 5 sample cartridges
- 1 cuvette

#### Procedure

1. Load the calibration carousel as follows:

Position 1	Empty Sample Cartridge and Cuvette
Position 2	Probe-Positioning Cartridge
Position 5	Empty Sample Cartridge
Position 10	Empty Sample Cartridge
Position 15	Empty Sample Cartridge
Position 20	Empty Sample Cartridge

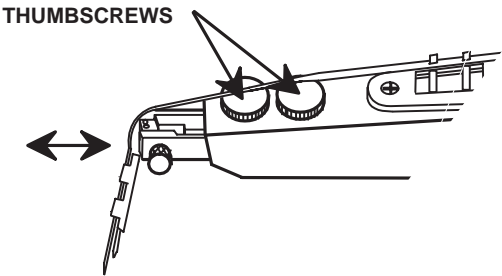
Lock the carousel

2. Install the **batch pack adapter**.
3. Remove the vial caps from the 3-pot reagent pack, and place the reagent pack in the analyzer.

4. Place the carousel into the instrument. Leave the access door open.

Step	Operator Action	System Response
A	Press <b>TEST 3.10 RUN</b>	<div>AUTO BOOM CAL</div> <ul style="list-style-type: none"><li>• Boom seeks home.</li><li>• Carousel rotates.</li><li>• Barcode reader finds the edge of the carousel label holder.</li><li>• Carousel rotates.</li><li>• Barcode reader locates carousel barcode.</li><li>• Carousel rotates.</li><li>• Boom moves home.</li></ul> Probe stops over “P” vial.
B	<p>Adjust the left-to-right positions of the boom arm for all locations.</p> <p>Press “.” (right) 0 (left)</p> <p>When the correct position is obtained press <b>STORE</b></p> <p>Repeat left-to-right adjustment for: T vial S vial Waste/Wash Station Sample Well</p> <p>Verify that position is correct press <b>STORE</b></p>	<div>ADJUST POSITION</div> <p>The boom moves left or right, records the position, and moves the boom to the next position.</p> <p>Moves to:</p> <p>“T” vial “S” vial Waste/Wash Station Sample Well</p> <p>Probe drops down to the bottom of the sample well.</p> <p>Carousel moves to position 2 probe-positioning cartridge. Probe moves to predilution well position.</p>

Step	Operator Action	System Response
C	Press <b>6</b> (down) DO NOT force the probe into the cartridge opening  <u>IF POSITION CORRECT:</u> Press <b>STORE</b> Proceed to <b>step D</b> .	The probe moves down in step increments.   The program records the Dilution Well <b>System 3.4</b> parameter.  The probe moves to the cuvette position.
	<u>IF POSITION INCORRECT LEFT-TO-RIGHT:</u> Press “.” (right) <b>0</b> (left)  Return to the beginning of Step C.  <u>IF POSITION INCORRECT FRONT-TO-BACK:</u> Refer to the following procedure.  <u>Front-to-Back Probe Positioning</u> <ol style="list-style-type: none"><li>1. Support the underside of the boom assembly to avoid damaging the probe tip. Loosen the thumbscrews on top of the boom arm 1/8 to 1/4 turn.</li><li>2. Move the probe holder in or out of the boom arm as needed to position the probe in the probe-positioning cartridge opening.</li><li>3. Supporting the underside of the boom arm, hold the probe and tighten the two knurled thumbscrews to secure the probe.</li><li>4. Press <b>STOP</b> and repeat the positioning procedure beginning with <b>Step A</b>.</li></ol>	The probe moves up then to the right or left.



Step	Operator Action	System Response
D	Adjust probe position Press “.” (right) 0 (left) STORE	<p>The carousel records Cuvette Position (Sys 3.5)</p> <p>600 µL is dispensed into dilution well of cartridge 1.</p> <div>DISPENSING</div> <p>5 aliquots of 50 µL each are dispensed from the dilution well of cartridge 1 to the sample wells of cartridges 1, 5, 10, 15 and 20.</p>
E		<div>Z-BOOM LEVEL = XXX</div> <p>Probe dips into each of the 5 sample wells verifying that each LLS is 172 or 173. If the LLS is not 172 or 173 the instrument will adjust the Z-boom home position and again check if the LLS at each sample well is 172 or 173. If the LLS at each sample well does not equal 172 or 173 after 5 tries, then “BOOM OUT OF SPEC” is reported.</p>
	<p><u>IF BOOM CAL PASSES:</u></p> <p>Remove the carousel and discard the waste.</p>	<div>BOOM CAL PASSED</div> <p>Report is printed. Stores all previously recorded values.</p> <div>READY</div> <p>OR</p>
	<p><u>IF BOOM CAL FAILS:</u></p> <p>Refer to Section 6.0 Printed Error Codes for corrective action.</p> <p>Remove the carousel and discard the waste.</p>	<div>BOOM OUT OF SPEC</div> <p>Report is printed.</p> <div>READY</div>

### Test 3.11 - Reserved for Future Applications

### Test 3.12 - Reset Pointers

This test procedure erases all data stored in memory by the spooler.

**NOTE:** This procedure should not be performed unless requested by the **Customer Support Center**.

Press **TEST 3.12 RUN** to initiate this activity. The S = X% message is erased from the display.

### Test 3.13 - Reagent Carousel Calibration

This diagnostic test determines and stores the correct positions for the movement of the boom and the reagent carousel (**Systems 10.1 through 10.5**).

### Materials Needed

- Reagent carousel
- Wedge reagent pack

### Procedure

1. Select a reagent carousel.
2. Remove the vial caps or snap caps, and place a reagent wedge pack in Location A of the reagent carousel.
3. Place the reagent carousel into the instrument. Leave the access door open.
4. Press **TEST 3.13 RUN**.
5. When [SYS 3 PARAMS OK?] appears in the display, the system is asking whether a boom calibration has been performed in the batch mode of operation. If this has been done, press **STORE**, and [RGT CRSL CAL] will be displayed.

The reagent carousel rotates and stops, then the probe is positioned over the "S" vial.

**NOTE:** If a batch mode boom calibration has not been performed, press **STOP** and perform the boom calibration (**Test 3.2**) prior to performing the reagent carousel calibration.



6. When [ADJUST POSITION] appears in the display, center the probe over the vial by pressing the following keys:

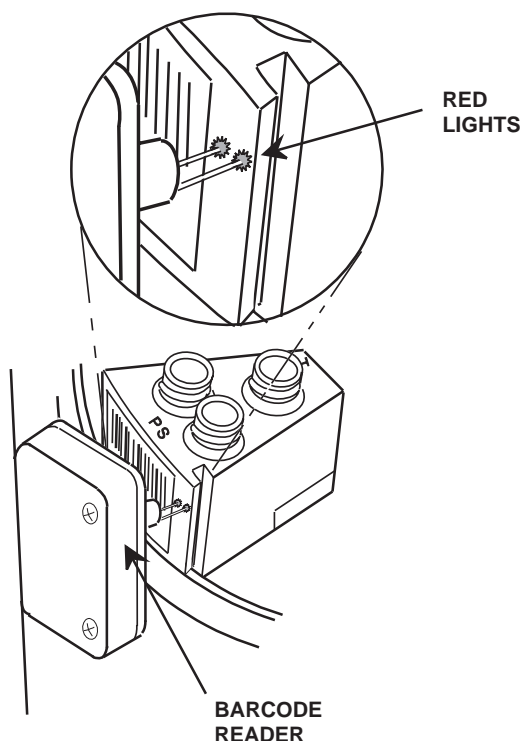
- 0** - moves the probe left by steps
- “.”** - moves the probe right by steps
- 1** - moves the reagent carousel clockwise by steps
- 2** - moves the reagent carousel counterclockwise by steps

Once the correct position is obtained, press **STORE**.

7. The reagent carousel rotates and places the reagent wedge pack by the reagent barcode reader.

- 0** - moves the reagent carousel clockwise
- “.”** - moves the reagent carousel counterclockwise

Press **“.”** until the two red lights appear on the right edge of the reagent wedge pack. If the red lights are on the barcode label, press the **0** key to rotate the reagent carousel clockwise to position the red lights on the edge of the reagent wedge pack. The red lights should appear on the edge of the reagent wedge pack, not on the barcode label.



8. When proper location is determined, press **STORE**. Calibration is completed, and the system returns to [READY].
9. Press **SYSTEM 10 PRINT** for a printout of the new **System 10.1** through **10.5** parameters for future reference.

**NOTE:** The boom and reagent carousel positions stored during this procedure cannot be verified by running another reagent carousel calibration. Doing so would recalibrate rather than verify. To check these positions, perform a random access **buffer run** (Test 3.14) or use **TEST 4.7** of the hand controls.

Test 3.14 - Buffer Run

This diagnostic test provides the operator the opportunity to observe the dispensing process of the instrument. Through this observation, the operator can note probe positioning in the reagent wedge pack vials, the sample well, and the predilution well. This procedure differs from the Dispense Check (**Test 6.3**) in that all initial checks are performed by the TDxFLx<sup>®</sup> System.

Materials Needed

- 8 Wedge reagent packs filled with buffer
- Reagent carousel
- Sample carousel
- Sample Cartridges
- Cuvettes
- 50 µL pipette
- X SYSTEMS<sup>®</sup> Dilution Buffer

Procedure

1. Remove vial caps or snap caps. Place the wedge pack(s) filled with buffer on the reagent carousel. Place the reagent carousel into the instrument.
2. Prepare a sample carousel with sample cartridges and cuvettes. Ensure that there is a cuvette for every cartridge on the carousel. Pipette a minimum of 50 µL of X SYSTEMS<sup>®</sup> Dilution Buffer into the sample wells. Place the sample carousel in the instrument.
3. Disable the door sensor:
  - a. Ensure the display is at [READY].
  - b. Press **SYSTEM 2.2 EDIT 0 STORE**.
  - c. Press **STOP** to return to [READY].
4. Leave the access door open and press **TEST 3.14 RUN**.
5. The display updates briefly with [ENTER RGT LDLIST] followed by [A=       \_ \_ ]. Enter the two-digit number of the desired assay found in Location A of the reagent carousel and press **STORE**.
6. The display reads [B=       \_ \_ ]. Repeat Step 5 for all wedge buffer pack locations.
 

**NOTE:** The operator may press **NEXT** to advance or to skip locations on the reagent carousel.
7. Press **RUN** after the last entry, if this wedge is not in Location H. If the last wedge pack is in Location H, the reagent list prints automatically.

8. The display updates with [REAGENT LIST OK?]. If the list is correct, press **STORE**. If the list is incorrect, press **NEXT**, and repeat **Steps 5-7**.
9. The display momentarily reads [ENTER SAMPLE LST] and follows with [LOC 1 ASSAY # \_ \_]. Enter the assay to be observed in Position 1 by pressing its corresponding assay key on the reagent display keypad or by entering the two-digit assay number and pressing **STORE** after each entry.
10. The display reads [LOC 2 ASSAY # \_ \_]. Repeat Step 9 for all assays that require observation.
11. Press **RUN** after the last entry. The display reads [ASSAY LIST OK?]. If the list is correct, press **STORE**. If the list is incorrect, press **NEXT** and repeat Steps 9 through 11.

Observe the dispensing operation for the following:

- a. Proper probe positioning in the reagent wedge pack vials
- b. Splashing in the predilution well
- c. Foaming in the predilution well
- d. Probe properly centered in the sample well
- e. Probe properly positioned in the predilution well

If splashing and foaming are observed, carefully check the condition and position of the probe as described in **Section 5.0 Maintenance**.

If the probe is not properly centered over the reagent wedge vials, perform the Reagent Carousel Calibration (**Test 3.13**) previously described.

12. Enable the door sensor:
  - a. Ensure the display is at [READY].
  - b. Press **SYSTEM 2.2 EDIT 1 STORE**.
  - c. Press **STOP** to return to [READY].

EXAMPLE PRINTOUT OF TDxFLx<sup>®</sup> BUFFER RUN

***TDXFLX BUFFER RUN***			
**TDXFLX REAGENT CAROUSEL LOADLIST**			
RGT			EXP
LOC	REAGENT	RGT LOT #	DATE
A	GENTAMICIN		
B	TOBRAMYCIN		
TDXFLX RUN SAMPLES			
DATE:			
TIME:			
SERIAL #:			
LOCK = 0			
SAMPLE LOADLIST			
LOC	1	GENTAMICIN	
LOC	2	TOBRAMYCIN	
LOC	ASSAY	PATENT-ID	CONC
1	GENT	1231231231	BUFFER RUN
2	TOBRA	321	PREDIL LOW

Test 3.15 - Batch Buffer Run

Buffer run is used in the batch mode to observe the dispensing process of the instrument to note probe position in the sample well and the predilution well. This run also observes the mixing action in the predilution well. This procedure differs from the dispense check (Test 6.3) in that all initial checks are performed by the TDxFLx<sup>®</sup> System.

Materials Needed

- Batch reagent pack filled with buffer
- Batch-pack adapter
- Sample carousel
- Sample cartridges
- Cuvettes
- Pipet capable of delivering the appropriate sample volume for the selected assay
- X SYSTEMS<sup>®</sup> Dilution Buffer

Procedure

1. Install the **batch-pack adapter**.
2. Remove the vial caps, and place the batch reagent pack into the instrument.
3. Prepare a carousel with several sample cartridges and cuvettes, then place X SYSTEMS<sup>®</sup> Dilution Buffer into the sample wells. Place the carousel into the instrument. (A minimum volume of buffer specified for the selected assay may be used to troubleshoot a sample-skipping problem or verify that a minimum fluid volume will be sensed. Refer to the appropriate assay manual insert for minimum sample volume values.)
4. Disable the door sensor:
  - a. Ensure the display is at [READY].
  - b. Press **SYSTEM 2.2 EDIT 0 STORE**.
  - c. Press **STOP** to return to [READY].
5. Leave the carousel access door open and press **TEST 3.15 RUN**. The display updates with

ASSAY #                      -- --
------------------------------------

Enter the two-digit number of the assay to be observed and press **STORE**.

- 6. Observe the dispensing operation for the following:
  - a. Splashing in the predilution well
  - b. Foaming in the predilution well
  - c. Probe properly centered in the sample well
  - d. Probe properly positioned in the predilution well
  - e. Probe properly positioned in the reagent vials

If splashing and foaming are observed, carefully check the condition and position of the probe as described in **Section 5.0 Maintenance**.

If the probe is not properly centered over the reagent vials, perform the Automated Probe Positioning and Boom Calibration (**Test 3.10**) previously described.

- 7. Enable the door sensor:
  - a. Ensure the display is at [READY].
  - b. Press **SYSTEM 2.2 EDIT 1 STORE**.
  - c. Press **STOP** to return to [READY].

EXAMPLE PRINTOUT OF TDxFLx® **BATCH BUFFER RUN**

***BUFFER RUN***			
DATE:			
TIME:			
SERIAL #:			
LOCK = 0			
OP ID:			
RGT LOT #:			
ASSAY: THEOPHYLLINE			
CAROUSEL: 14			
SPLVOL= 2.00			
REPS= 1			
GAIN= 40			
CALIB.DATE:			
CALIB.TIME:			
CONC= UG/ML			
SAMPLES			
LOC	CONC	NET P	BLK I
1	BUFFER RUN		
2	BUFFER RUN		
3	INSUFFICIENT SPL		
4	BUFFER RUN		
5	BUFFER RUN		

### Test 4 - Hand Controls

**CAUTION:** The hand controls should be used only by an Abbott trained operator or with the assistance of the **Customer Support Center** or Field Service Engineer.

Test 4 allows the operator to control the mechanical operation of all stepper motors and monitor the status of the optical, temperature control, and barcode systems. These tests do not make any permanent changes in system memory.

Each test uses the keypad to control specific functions or monitor specific parameters. The display shows various status information to assist the operator during the test.

To obtain a listing of the hand-control tests, press **TEST 4 PRINT**. The following diagnostic tests are printed:

Test 4.1 - REVOLVER (Sample Carousel Movement)

Test 4.2 - PHOTOMETER (Optics Assembly)

Test 4.3 - PUMPER (Dispenser Assembly)

Test 4.4 - BOOMER (Boom-Arm Movement)

Test 4.5 - TEMP HNDLR (Temperature System)

Test 4.6 - BARCODE CHK (Barcode Check)

Test 4.7 - REAGENT CAR (Reagent Carousel Movement)

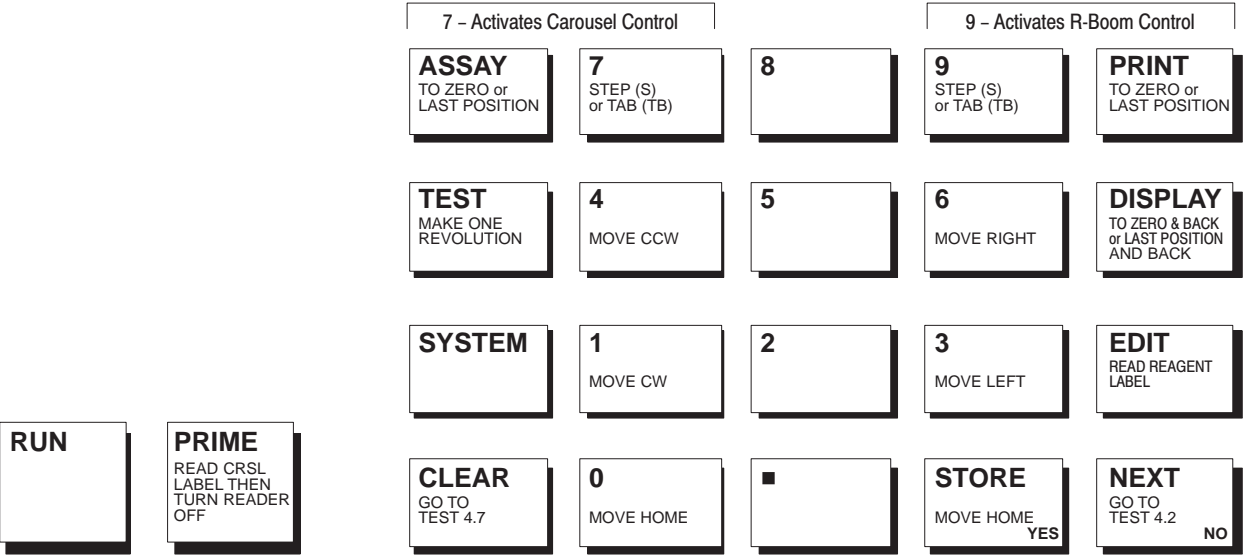
#### Test 4.1 - Revolver (Sample Carousel Movement)

The carousel and R-boom (horizontal) stepper motors can be controlled by using this test. To activate this test, press **TEST 4.1 RUN**. Use the keys on the right side of the keypad to control the R-boom movement and the keys on the left side to control the carousel movement.

- To activate revolver test:

Press **TEST 4.1 RUN**.

**NOTE:** If the R-boom control has been activated, the carousel control will be regained by pressing **7**.



TEST 4.1 - REVOLVER

- To control carousel movement:
  - Press **7** to activate carousel control. Three messages are displayed:

[HC = H or N] - indicates whether the carousel is at the home (H) position or not (N).

[C = Y or N] - indicates whether the cuvette or carousel locking tab is being sensed by the optical sensor (Y) or not (N).

[S= or TB=] - indicates the number of steps (S) or tabs (TB) the carousel stepper motor has moved to reach the present position.

**NOTE:** One tab (TB) is equal to 86 steps for the carousel stepper motor. The tab number indicates which carousel location is presently at the dispense axis.  
Example: [TB=1] indicates that the sample cartridge in Position 1 is at the dispense axis.
  - When [S=] is displayed and **1** or **4** is pressed, the stepper motor moves one step. When [TB=] is displayed and **1** or **4** is pressed, the motor moves 86 steps.



- To control R-boom movement:
  1. Press **9** to activate R-boom control. Three messages are displayed:

[HR = H or N] - indicates whether the R-boom is at the home (H) position or not (N).

[R = B or W] - indicates whether the barcode reader is detecting black (B) or white (W).

[S= or TB=] - indicates the number of steps (S) or tabs (TB) the R-boom stepper motor has moved to reach the present position. One tab (TB) is equal to 30 steps for the R-boom stepper motor.

If the carousel control is at [TB= ], you enter R-boom control at [S= ]. The reverse is also true.

**CAUTION: To avoid damaging the probe, the Z-boom must be at home before you can move the R-boom or the carousel. (Use **Test 4.4** to home the Z-boom or press STOP PRIME).**
  2. When **EDIT** is pressed, the barcode reader is turned on and the boom arm moves to the position designated as the start of the reagent pack barcode and reads the label. The display alternates between the batch-pack label name and the 13-digit barcode number.
  3. When [S=] is displayed and **6** or **3** is pressed, the stepper motor moves one step. When [TB=] displays and **6** or **3** is pressed, the stepper motor moves 30 steps.
  4. When [S=] displays and **3** or **6** is pressed, the appropriate stepper motor will move one step. The step number in the display does not update until the key is released. If you wish to move the motor one step at a time when moving the R-boom or carousel to a particular step location, release the key quickly after pressing it.

5. The **PRIME** key is active only during R-boom control when [HR=] is displayed. The carousel label is read when this key is pressed, and the display reads [BAR AMPL] followed by a number greater than 20. The display then alternates between the carousel label number and the amplification value. (The X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set carousel reads 13, a calibration carousel reads 14, a unit dose calibration carousel reads 15, and a unit dose assay carousel reads 16.)

**NOTE:** The **ASSAY**, **TEST**, **PRINT**, and **EDIT** keys each control two actions. The action depends on the present location of the stepper motor. If the stepper motor is at zero when the key is pressed, the second action occurs. If the stepper motor is not at zero, when the key is pressed, the first action occurs.

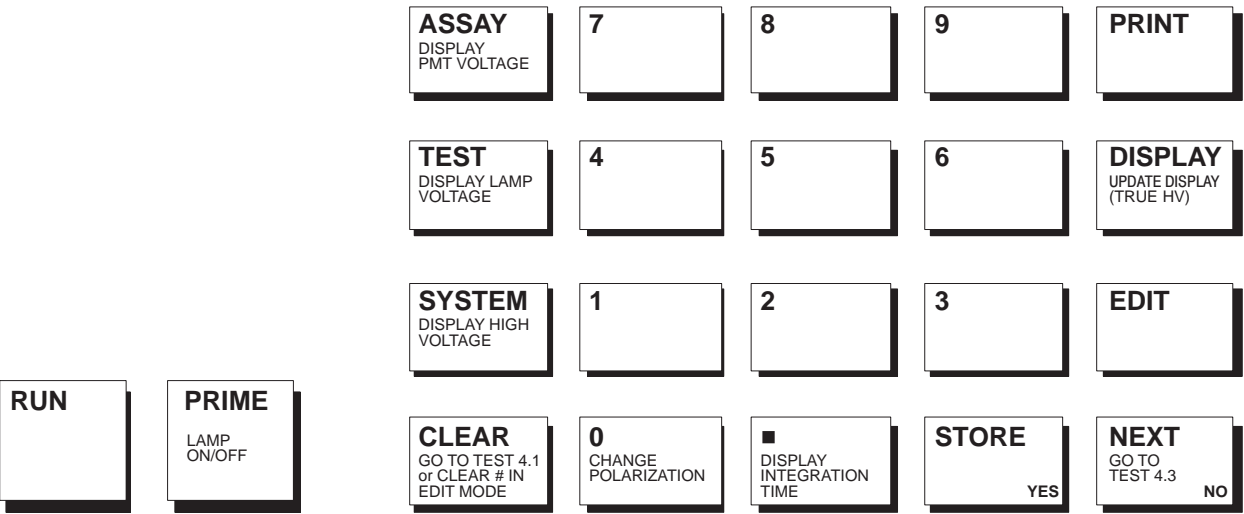
6. Press **STOP** to return to [READY].

Test 4.2 - Photometer (Optics Assembly)

This test allows the voltage of the PMT, source lamp, and high-voltage (HV) power supply to be displayed. The operator can also turn the lamp on and off, change the voltage to the HV power supply, and change the orientation of the polarized light with the appropriate keys.

- To activate this test, press **TEST 4.2 RUN**. The display reads [PHOTOMETER]. When this test is entered, the integration time is automatically set to 100 msec, and the high voltage is automatically set to half scale (500).

The desired measurement can be obtained by pressing the appropriate key as illustrated below.



TEST 4.2 - OPTICS ASSEMBLY

- Once a voltage key is pressed, the **left** side of the display shows which system has been selected through the keypad:  
PMT    photomultiplier tube voltage  
TIME   integration time  
LMP    source lamp voltage  
HV     high-voltage power supply

- The center of the display shows the numeric value for the system selected through the keypad.
- The right side of the display shows the current status of two items:
  1. The orientation of the polarized light:  
H = horizontal      V = vertical
  2. Status of the lamp:  
\* = lamp on      (blank) = lamp off  
  
To turn the lamp on, press **PRIME**.  
  
When the PMT voltage is displayed, the letter N or U indicates:  
N = The lamp is on and the PMT voltage has been normalized (N) by dividing the lamp reference voltage into the PMT voltage.  
U = The lamp is off and the PMT voltage is unnormalized (U).
  3. Press **STOP** to return to [READY].

Test 4.3 - Pumper (Dispenser Assembly)

The dispenser system can be controlled using this test. The control keypad is divided into a left and right side. The keys located on the left side control the diluent syringe while the keys on the right side control the sample syringe. The keypad functions are illustrated below.

RUN

PRIME

7 – Activates Diluent Syringe Control

ASSAY  
TO ZERO or  
LAST POSITION

7  
STEP (S)  
or TAB (TB)

8

TEST  
TO ZERO & BACK  
or LAST POSITION  
AND BACK

4  
MOVE DOWN

5

SYSTEM

1  
MOVE UP

2

CLEAR  
GO TO  
TEST 4.2

0  
MOVE HOME

9 – Activates Sample Syringe Control

9  
STEP (S)  
or TAB (TB)

PRINT  
TO ZERO or  
LAST POSITION

6  
MOVE DOWN

3  
MOVE UP

STORE  
MOVE HOME  
YES

NEXT  
GO TO  
TEST 4.4  
NO

TEST 4.3 - DISPENSER ASSEMBLY

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- Press **TEST 4.3 RUN** to activate control of the syringes.
- Press **7** to activate diluent syringe control.

**NOTE:** If the sample syringe control has been activated, diluent syringe control can be regained by pressing **7**.

**CAUTION:** Before moving the syringes, place a test tube or other receptacle under the probe in order to prevent spills in the system.

When diluent syringe control is active, the display shows three status messages:

[HD = H or N] - indicates whether the diluent syringe is at the home (H) position or not (N).

[V = H or N] - indicates whether the valve is at the home (H) position or not (N).

[S= or TB=] - indicates the number of steps (S) or tabs (TB) that the stepper motor has moved to reach the present position. One tab (TB) equals 30 steps.

Press **9** to activate sample syringe control. The display shows three status messages:

[HS = H or N] - indicates whether the sample syringe is at the home (H) position or not (N).

[B = Y or N] - indicates whether the buffer platform is activated (Y) or not activated (N). (When there is sufficient buffer to run an assay, the microswitch is activated.)

[S= or TB=] - indicates how many steps (S) or tabs (TB) the stepper motor moved to reach the present position. One tab equals 30 steps. If diluent syringe control was at [TB=], you enter sample syringe control at [S=]. The reverse is also true.

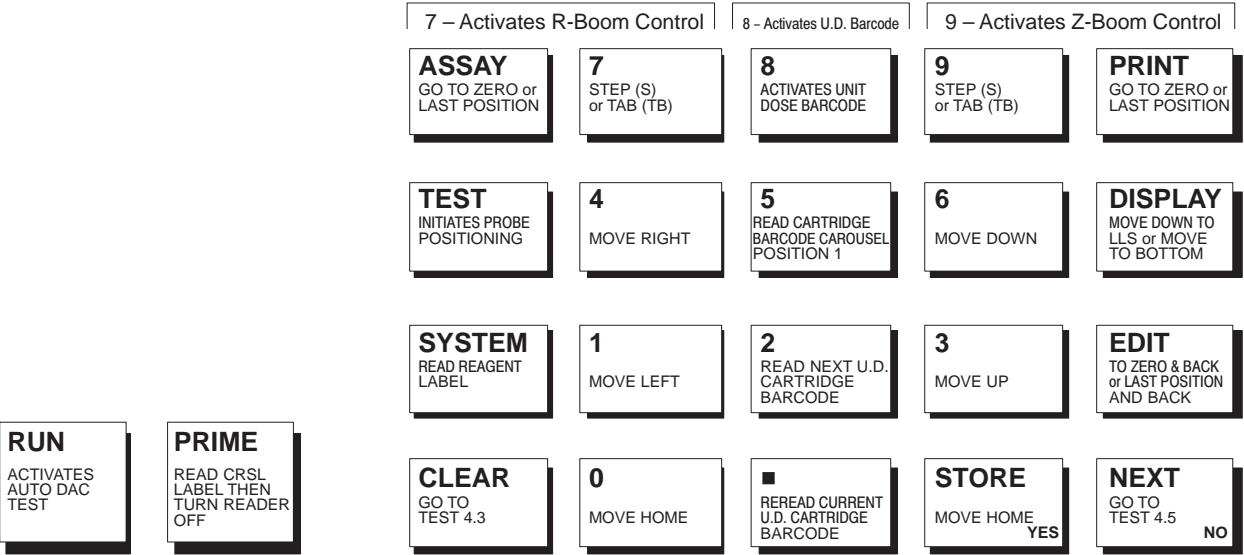
**CAUTION:** Before moving the syringes, place a test tube or other receptacle under the probe in order to prevent spills in the system.

**NOTE:** For Test 4.3 the **ASSAY**, **TEST**, **PRINT** and **EDIT** keys each control two actions. The action depends on the present location of the syringe plunger. If the plunger is at zero, the second action occurs when the key is pressed. If the plunger is not at zero, the first action occurs when the key is pressed.

Press **STOP** to return to [READY].

Test 4.4 - Boomer (Boom-Arm Movement)

The horizontal (R-boom) and vertical (Z-boom) movement of the boom arm and the reading of unit dose cartridge barcodes can be controlled with this test. The keys located on the left side of the keypad control the R-boom (horizontal) movement while the keys on the right side of the keypad control the Z-boom (vertical) movement. The keypad functions are illustrated below.



TEST 4.4 - BOOM-ARM MOVEMENT

- Press **TEST 4.4 RUN** to activate control of boom-arm movement.
- Activate R-boom (horizontal) control as follows:
- Press **TEST 4.4 RUN**. If the Z-boom control is active, R-boom control can be regained by pressing **7**. When you are in control of the R-boom, the display shows three status messages:

[HR = H or N] - indicates whether the R-boom is at the home (H) position or not (N). HR appears to the left of the H or N to indicate that the R-boom control is active.

[R = B or W] - indicates whether the barcode reader is detecting black (B) or white (W).

[S= or TB=] - indicates the number of steps (S) or tabs (TB) the stepper motor moved to reach the present position. One tab is equal to 30 steps.

- Activate Z-boom (vertical) control as follows:
- Press **9**. When you are in control of the Z-boom, the display shows three status messages:
  - [HZ = H or N] - indicates whether the Z-boom is at the home (H) position or not (N). HZ appears to the left of the H or N to indicate that the Z-boom control is active.
  - [L = Y or N] - indicates whether the fluid-sensing electrodes are sensing liquid (Y) or not (N).
  - [S= or TB=] - indicates the number of steps (S) or tabs (TB) the stepper motor moved to reach the present position. One tab is equal to 30 steps. If the R-boom control is at [TB=], you enter Z-boom control at [S=]. The reverse is also true.

**CAUTION: Z-boom must be at home before the R-boom or carousel can be moved. To return the Z-boom to home, press 9 and STORE.**

- Activate unit dose cartridge barcode control as follows:
  1. Press **8** when the display reads [HR=]. The display changes to [U.D. BARCODE].
  2. Press **5**. The system reads the unit dose cartridge barcode in Position 1. The display alternates between [ASSAY NAME] and [BAR AMPL #].
  3. Press **2**. The system reads the next unit dose cartridge barcode. You can advance the carousel, but you cannot reverse it.
  4. To reread the same cartridge, press “.”.
  5. Press **STOP** to return to [READY].

**NOTE:** The **ASSAY**, **PRINT**, **DISPLAY** and **EDIT** keys each control two actions. The action depends on the present location of the boom arm. If the boom arm is at zero when the key is pressed, the second action occurs. If the boom arm is not at zero when the key is pressed, the first action occurs.

**NOTES:** The **TEST** key initiates the **probe-positioning check and adjustment**.

The **RUN** key activates the Auto DAC test.

When [S] is displayed and keys **1, 3, 4, or 6** are pressed, the appropriate stepper motor moves one step. The step number in the display **does not** update until the key is released. If you wish to move the motor one step at a time when you are moving the R-boom or Z-boom to a particular step location, release the key quickly after pressing.

The **8** key is active only during R-boom control. Pressing **8** activates the ability of the boom-arm barcode reader to locate the unit dose cartridge barcode.

Test 4.5 - Temp Hndlr (Temperature System)

This diagnostic test allows the operator to display the voltage and temperature of the three heater systems by pressing the appropriate key as illustrated below. The ground, thermopile, and 5-volt values can also be displayed by pressing the appropriate key.

ASSAY  
DISPLAY  
THM OFF

7

8

9

PRINT

TEST  
DISPLAY (UPDATE)  
OPTICS  
HEATER VOLT

4

5  
DISPLAY (UPDATE)  
SELECTED  
TEMP

6

DISPLAY

SYSTEM  
DISPLAY (UPDATE)  
AIR HEATER  
VOLT

1  
DISPLAY  
SYSTEM GROUND

2  
DISPLAY  
SYSTEM 5 VOLT

3

EDIT

RUN

PRIME

CLEAR  
GO TO TEST 4.4  
or CLEAR # IN  
EDIT MODE

0

■

DISPLAY  
INTEGRATION  
TIME

STORE  
STORE or TURN  
HEATER  
ON/OFF YES

NEXT  
GO TO  
TEST 4.6 NO

TEST 4.5 - TEMPERATURE SYSTEM

- Activate the temperature system as follows:
  1. Press **TEST 4.5 RUN**. The display reads [TEMP HNDLR]. When this test is entered, the integration time is automatically set to 100 msec.



2. Press the appropriate key (See **keypad functions for Test 4.5**) to obtain the desired measurements.
  - The left side of the display shows which system has been selected:

THMO	- Thermopile Voltage
OPT	- Optics Heater
AIR	- Air Heater
LIQ	- Liquid Heater
SYS GND	- System Ground Voltage
SYS 5V	- System 5V Voltage Reading
  - The center of the display shows either the voltage [V=] or the temperature [T=] of the selected system.
  - The right side of the display indicates whether the selected heater system is ON or OFF. The **STORE** key temporarily turns the heater on if it is off or off if it is on; however, the change does not show until the display is updated by pressing **5**.
3. To display the temperature of a heater system, press the appropriate key for the heater voltage, then press **5**.
4. Press **STOP** (press **CLEAR** first if editing) to return to [READY].

#### Test 4.6 - Barcode Chk (Barcode Check)


This diagnostic test is for factory use only.

Test 4.7 - Reagent Car (Reagent Carousel Movement)

This test provides hand controls to move the reagent carousel. These controls are used to perform the reagent carousel calibration detailed below. This test provides hand controls to activate the reagent carousel, R-boom (horizontal), and Z-boom (vertical ) movements. Keypad functions are illustrated below.

RUN

PRIME  
READ  
CAROUSEL  
BARCODE

Reagent Carousel		Z-Boom	R-Boom	
ASSAY ZERO or LAST POSITION	7 STEPS VIAL WEDGE	8 STEP (S) or TAB (TB)	9 STEP (S) or TAB (TB)	PRINT GO TO ZERO or LAST POSITION
TEST MOVE ONE REVOLUTION	4 MOVE CCW	5 MOVE DOWN	6 MOVE RIGHT	DISPLAY ZERO LAST AND BACK
SYSTEM READ REAGENT BARCODE	1 MOVE CW	2 MOVE UP	3 MOVE LEFT	EDIT LLS
CLEAR GO TO TEST 4.6	0 HOME REAGENT CAROUSEL	 HOME Z-BOOM	STORE HOME R-BOOM YES	NEXT GO TO TEST 4.1 NO

TEST 4.7 - REAGENT CAROUSEL MOVEMENT

The movement of the reagent carousel can be controlled in three functions: step, vial, and wedge. Each of these functions can be accessed by pressing the **7** key until the corresponding function appears on the system control display.

Press **TEST 4.7 RUN** to activate the test.

1. Press the **7** key to activate the movement of the reagent carousel by steps, by vial, or by wedge.
2. Press the **0** key to home the carousel.
3. Use the **4** key to move the carousel counterclockwise.
4. Use the **1** key to move the carousel clockwise.

To activate the following controls from the [READY] state, press **TEST 4.7 RUN 0**.

### Barcode Reading

1. Press the **SYSTEM** key to read one wedge barcode label at a time. Location of the wedge (A through H) along with its corresponding 13-digit number should be displayed on the main display. The assay name displays on the reagent display.
2. Press the **9** key and all wedges on the reagent carousel are read and the corresponding assay names are displayed on the reagent display.
3. Press the “.” key to exit the barcode-reading mode.
4. Press **PRIME** to read sample-carousel barcode label.
5. Press the **0** key to activate the reagent carousel mode.

### Z-Boom Control

1. Press the **8** key to activate liquid-level sensing. Pressing the **8** key alternates from steps (S=XXX) to tabs (T=X).
2. Press the **5** key to bring probe down one step or tab (86 steps) at a time.
3. Press the **2** key to bring probe up one step or tab at a time.
4. The **EDIT** key initiates liquid sensing.
5. Press the “.” key to home Z-boom. Display should read: [HZ=H L=N TB=X] or [HZ=H L=N S=XXX]

### R-Boom Control

1. Press the **9** key to activate lateral movement of boom arm.  
**NOTE:** Z-boom must be at home before R-boom will move. The display is updated with:  
 [HR=H R=W S=X] or [HR=N R=W TB=X]
2. Use the **6** key to move the boom arm left to right one step or one tab (30 steps) at a time.
3. Use the **3** key to move the boom arm right to left one step or one tab (30 steps) at a time.
4. Press **STORE** to position the boom arm at its home position.  
**PRINT:** Moves the boom arm to position 0 or to the last position.  
**DISPLAY:** Moves the boom arm to position 0 and back or last position and back.

### Test 5 - Board Tests

Diagnostic tests for the boards are designed to verify board integrity. Do not perform these tests without first contacting your **Customer Support Center**.

Test 5.1 REPEAT RUN - Runs all Test 5 programs continuously, except for front panel, long print, motor board, and UART tests.

5.1.1 SINGLE RUN - Starts at the beginning of Test 5 and executes one test at a time, except for front panel, motor board, and UART tests.

Test 5.2 COMPUTER BOARD

5.2.1 PROM TEST

5.2.2 RAM TEST

Test 5.3 MEMORY BOARD 1

5.3.1 PROM TEST 1

5.3.2 NOVRAM TEST 1

Test 5.4 PRINTER & DRIVER

5.4.1 LONG PRINT TEST - Prints 10 rows of all printhead pins across the paper.

5.4.2 SHORT PRINT TEST - Prints one row with each of the seven printhead pins individually.

Test 5.5 I/O BOARD (Input/Output Board)

5.5.1 UART TEST - Requires loop back connector.

5.5.2 CTC TEST (Counter-Timer Circuit)

5.5.3 WASTE CUP TEST

Test 5.6 FRONT PANEL

5.6.1 KEYBOARD TEST - Checks each key on the keyboard and displays value of key. Press **STOP** twice to end the test.

5.6.2 DISPLAY TEST - Checks all dots of the front panel display.

Test 5.7 MTR BOARD

Checks the sensors and motors on the triple motor (motor driver) boards. This routine also checks part of the analog/optics board related to the optics system.

### Test 6 - Special Tests

With the exception of Test 6.3 Dispense Check, Test 6.4 Turbo<sup>®</sup> Correction Factor Entry, Test 6.8 Probe Decontamination and Test 6.9 Panel Report, these tests are intended for factory testing and service ONLY. None of these tests should be performed without first consulting the **Customer Support Center**. Otherwise, damage to the instrument could result.

- 6.1 MEM BD NOVRAM
- 6.2 FACTORY SET
- 6.3 DISPENSE CHECK
- 6.4 **TURBO CF ENTRY**
- 6.5 ZERO CALIB CURVE
- 6.6 PRINT ALL PARAMS
- 6.7 F.T. CALC
- 6.8 **PROBE DECONTAM**
- 6.9 **PANEL REPORT**

### Test 6.3 - Dispense Check

**NOTE:** This test is only active in the batch mode on the instrument.

Test 6.3 can be used to observe many modes of pipetting (selected by the assay used) for splashing, carryover, probe positioning, or to check for any possible problems in the pipetting sequence. This test performs only Rev 1 and Rev 2 pipetting with a 5 second pause between them. The Dispense Check does not include Rev 0 pipetting, cuvette counting, barcode reading or intensity reading. All pots (reagents, sample, and predilute) are checked for LLS error. Any number of cuvettes can be run.

Do not run the Dispense Check procedure on pipetting modes that include Rev 0 pipetting (3, 7, 10, 23, 27, 31, 40 and 42). To determine the pipetting mode for a specific assay, press **ASSAY XX.18 DISPLAY**.

### Materials Needed

- Batch-pack adapter
- Batch reagent pack filled with dilution buffer
- X SYSTEMS<sup>®</sup> Dilution Buffer
- Cuvettes
- Sample cartridges

### Procedure

1. Load a carousel with the appropriate number of sample cartridges and cuvettes. Since there is no cuvette counting in this procedure, ensure that a cuvette is present for each sample cartridge.

2. For the assay being simulated, pipette the appropriate sample volume of X SYSTEMS<sup>®</sup> Dilution Buffer into each sample well. For example, a minimum of 250 µL of buffer should be used for Assay 10, Digoxin II.
3. Insert the **batch-pack adapter** and place a **reagent pack** containing X SYSTEMS<sup>®</sup> Dilution Buffer into the instrument.
4. Place the carousel into the instrument. Leave the carousel access door open.
5. Press **TEST 6.3 RUN**.
6. The system displays: [ASSAY NUMBER \_\_ ].

Refer to the reference assay list printout for the number of the assay required. If the list is not available, press **ASSAY PRINT**.

Enter the two-digit number for the assay required. Press **STORE**.

7. The display shows the assay name.
8. Test 6.3 then performs Rev 1 pipetting. The display reads:

REV 1 PIPETTING

9. At the completion of Rev 1 pipetting, the system performs Rev 2 pipetting. The display reads:

REV 2 PIPETTING

10. When the system completes Rev 2 pipetting for all samples, the pipetting sequence stops. The display reads: [READY].

#### Test 6.4 - Turbo<sup>®</sup> Correction Factor Entry

This test is used for Turbo<sup>®</sup> Specific Protein assays. Refer to the TDxFLx<sup>®</sup> & TDx<sup>®</sup> Turbo<sup>®</sup> Operation Supplement for additional information.

#### Test 6.8 Probe Decontamination

The probe must be decontaminated prior to servicing or removing the probe. Directions for performing the probe decontamination procedure are found in **Section 5.0 Maintenance** under Periodic Maintenance.

#### Test 6.9 Panel Report

This test prints all panels. The printout shows the panel number and all the assay names and numbers within that panel. Reference **Section 3.0 Operation** under Panel Programming/Printing for more information.

## Additional System Verifications

The following paragraphs detail additional system checks used to enhance operations of the TDxFLx<sup>®</sup> System.

### Coefficient of Variation (CV) Check

The purpose of this procedure is to check the within-run reproducibility.

#### Materials Needed

##### Batch

- Sample carousel
- Sample cartridges
- Cuvettes
- Batch-pack adapter
- Reagent pack
- Controls

##### Random Access

- Sample carousel
- Sample cartridges
- Cuvettes
- Reagent carousel
- Reagent pack
- Controls

#### Procedure

1. Load a sample carousel with 10 replicates of each of two levels of controls.
2. Batch
  - a. Ensure that the **batch-pack adapter** is installed properly.
  - b. Invert the appropriate reagent pack gently five times.
  - c. Remove the vial caps and place the reagent pack into the instrument.
  - d. Close the access door, and press **RUN**.

Random Access

- a. Insert the appropriate wedge reagent pack into the reagent carousel.
  - b. Mix by swirling. Remove the caps or snap cap.
  - c. Place the carousel into the instrument.
  - d. Close the access door, and press **RUN**.
3. At the completion of the assay, calculate the mean ( $\bar{x}$ ) and standard deviation (SD) for each level of control for both polarizations (P) and concentration results.
  4. Calculate the % CV for the concentration results on both levels of controls.

$$\% \text{ CV} = 100 \times \frac{\text{SD}}{(\bar{x})}$$

Specifications for acceptability:

- a. Concentration mean within range stated in the assays manual.
  - b. Concentration CV as stated in the appropriate assay section of the assay manual insert.
5. If results are not acceptable, refer to the Observed Problems under Erratic Test Results in **Section 6.0 Troubleshooting**.



### Background Subtraction Check

To verify that backgrounds are properly subtracted, follow the procedure below:

#### Materials Needed

##### Batch

- Batch-pack adapter
- Sample carousel
- 12 sample cartridges
- 12 sample cuvettes
- A calibrator
- Batch reagent pack
- X SYSTEMS<sup>®</sup> Dilution Buffer
- Pipet Check Solution

##### Random Access

- Reagent carousel
- Sample carousel
- 12 sample cartridges
- 12 sample cuvettes
- A calibrator
- Wedge reagent pack
- X SYSTEMS<sup>®</sup> Dilution Buffer
- Pipet Check Solution

#### Procedure

1. Place 12 sample cartridges and cuvettes into a sample carousel and lock the cuvettes into position.
2. Add a minimum of 50  $\mu$ L of the selected assay A calibrator to the sample wells of sample cartridges 1 and 2.
3. Add a minimum of 50  $\mu$ L of X SYSTEMS<sup>®</sup> Dilution Buffer to the sample wells of sample cartridges 3 through 7.
4. Add a minimum of 50  $\mu$ L of Pipet Check Solution to the sample wells of sample cartridges 8 through 12.
5. Batch
  - a. Place the sample carousel into the instrument.
  - b. Ensure that the **batch-pack adapter** is installed properly.
  - c. Invert the appropriate reagent pack gently five times.
  - d. Remove the vial caps and place the reagent pack into the instrument.
  - e. Close the access door, and press **RUN**.

Random Access

- a. Place the sample carousel into the instrument.
  - b. Insert the appropriate wedge reagent pack into the reagent carousel.
  - c. Mix by swirling. Remove the caps or snap cap.
  - d. Remove the batch-pack adapter, if applicable.
  - e. Place the reagent carousel into the instrument.
  - f. Close the access door, and press RUN.
6. At the completion of the assay, results should be as follows:
- | <u>BLK I</u>                | <u>NET P</u>   |
|-----------------------------|--|
| <u>Results</u>              | <u>Results</u>   |
| Cuvettes 3 - 7 Low values   | Same as AVG P for A Calibrator for selected assay ± 5 mP |
| Cuvettes 8 - 12 High values | Same as AVG P for A Calibrator for selected assay ± 5 mP |
7. If results are not within the stated limits, contact the Customer Support Center.

**Probe Performance - Carryover Check**

This diagnostic test checks the carryover of the probe. Carryover of 1.5% or less indicates the probe is performing properly.

**Materials Needed**

**Batch**

- Batch-pack adapter
- Sample carousel
- 5 sample cartridges
- 5 sample cuvettes
- Low and high controls
- Batch reagent pack

**Random Access**

- Reagent carousel
- Sample carousel
- 5 sample cartridges
- 5 sample cuvettes
- Low and high controls
- Wedge reagent pack

**Procedure**

1. Ensure that there is a valid calibration curve stored in memory for the assay suspected of carryover.
2. Place 5 sample cartridges and cuvettes into a sample carousel, and lock the cuvettes into position.
3. Load the appropriate controls into the sample wells as shown in the load list below:

<u>Position</u>	<u>Contents</u>
1	L Control
2	L Control
3	L Control
4	H Control
5	L Control

4. Batch

- a. Ensure that the **batch-pack adapter** is installed properly.
- b. Invert the appropriate reagent pack gently five times.
- c. Remove the vial caps and place the reagent pack into the instrument.
- d. Close the access door, and press **RUN**.

Random Access

- a. Insert the appropriate wedge reagent pack into the reagent carousel.
- b. Mix by swirling. Remove the caps or snap cap.
- c. Place the carousel into the instrument.
- d. Close the access door, and press **RUN**.

5. When the results are obtained, determine the percentage carryover (% c.o.) as described below:

Carryover (% c.o.)

- a. Average the results from Positions 1, 2 and 3.
- b. Calculate carryover (c.o.) from this formula:

$$\% \text{ c.o.} = \frac{(\text{pos. 5 result}) - (\text{average of 1, 2 and 3 results})}{(\text{Position 4 result})} \times 100$$

If the carryover is more than 1.5%, wash and dry the probe and repeat the **Probe Performance - Carryover Check**.

If the carryover is still more than 1.5%, **replace the probe**.

**Introduction**

This section identifies recommended maintenance requirements for the TDxFLx<sup>®</sup> System and details instructions for performing these procedures.

Maintenance requirements include:

- Daily Maintenance
- Weekly Maintenance
- Monthly Maintenance
- Periodic Maintenance
  - Quarterly Maintenance
- Component Replacement



**Daily Maintenance**

These procedures should be performed at the start of each day. If your system is to be used on multiple shifts, perform these procedures at the start of each 8-hour shift.

Record maintenance results as necessary in the maintenance log.

All daily maintenance procedures are described in the following pages:

- Empty and Wash Waste Container
- Inspect and Wash Probe
- Inspect Dispense Assembly
- Clean Waste/Wash Station
- Verify Unit Dose Probe Position

### Empty and Wash Waste Container

The instrument waste container is located underneath the left side of the instrument. Grasp the handle on the waste container. Pull the container to the left. Slip the retaining hook from the left rear leg of the instrument. Handle the container carefully to avoid spills. Empty the container and rinse thoroughly with water.

Replace the container by positioning the retaining hook around the left rear leg of the instrument. Position the container under the instrument by pushing the handle toward the right.

### Inspect and Wash Probe

#### Probe Inspection

1. Inspect the TEFLON<sup>®</sup> coated stainless steel probe from the front and the side. The tip should be pointed, not flared.
2. Check the TEFLON<sup>®</sup> coating on the stainless-steel probe for evidence of chipping or flaking. If the TEFLON<sup>®</sup> coating is chipped or flaked, **replace the probe**.

The coating may show signs of gradual wear on the front. This is normal and typically will not affect probe performance. Unless there are indications that the probe is not functioning properly, i.e., poor duplication or erratic test results, it is not necessary to replace the probe.

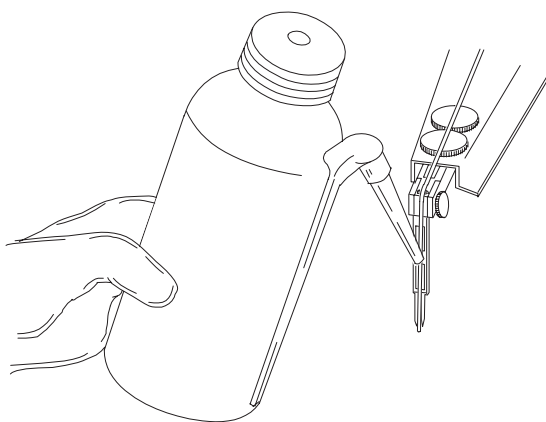
3. Inspect the fluid-sensing electrodes. If metal is exposed beyond the taper, replace them according to the procedure in the **Component Replacement** section.
4. When priming the system, raise the boom arm slightly so that the fluid stream is barely visible above the top of the waste/wash station. Inspect the probe for a straight liquid stream and any bubble formation or spraying.
5. If bubbles are forming at the probe tip or if liquid sprays outward from the tip, wipe the probe and repeat the priming.
6. If bubble formation is still present, wash the probe and inspect again during prime.
7. If bubbles persist, change the probe.



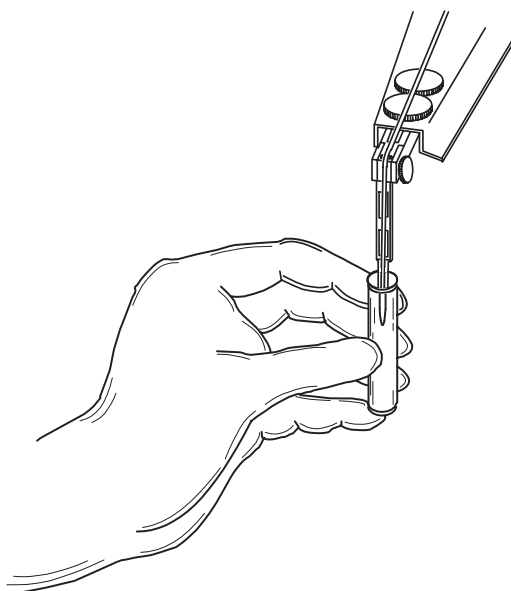
### Probe Wash

**CAUTION:** The probe and electrodes are sharp and contaminated with potentially infectious materials. Avoid contacting them.

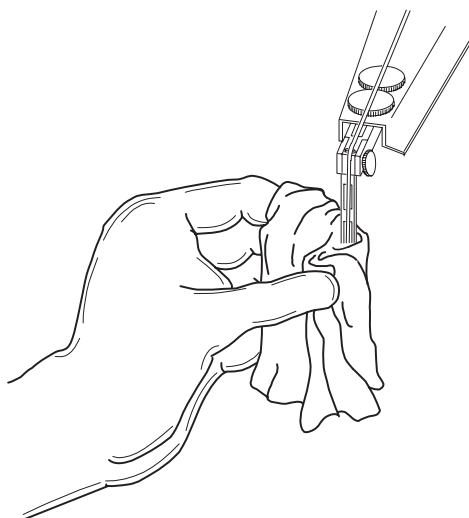
1. Remove the carousel and reagent pack if present.
2. Manually move the boom arm to the center of the instrument by grasping the barcode reader. Do not pull on the probe assembly.
3. Place an absorbent tissue underneath the probe. Rinse the probe by flushing it with deionized water. The water should run from the top of the detent to the bottom of the fluid-sensing electrodes.



4. Fill a cuvette with deionized water and immerse the probe tip into the water. Do not hit the tip of the probe against the cuvette.



5. Using a soft, lint-free tissue, blot the probe until it is dry. Ensure that the area between the probe and the fluid-sensing electrodes is dry.



6. To verify that the probe is dry:
  - a. Press **TEST 4.4 RUN 9**.
  - b. The display must read [L = N]. If it does not, repeat **Steps 3** through 6.
7. Prime several times to ensure that the tubing is filled with buffer and that the probe returns to its home position.

**NOTE:** For assays using whole blood, care should be taken to ensure that no dried blood remains on the probe after the wash.

#### Probe Wash Following REA<sup>®</sup> Assays

After REA Clinical Chemistry assays are run, the probe may be slightly discolored by the dyes used in the REA reagents. Following each REA assay or calibration run, perform this procedure:

1. Wet a lint-free tissue with deionized water, and gently wipe the outside of the probe and sensor tips. **DO NOT** bend the tip of the probe.
2. Clean the inside of the probe by pressing **PRIME** three times.
3. Blot the probe dry with a soft, lint-free tissue. Ensure that the area between the probe and the fluid-sensing electrodes is dry.

**Inspect Dispense Assembly**

1. Press **PRIME** three times.
2. Inspect for air bubbles and leaks in all tubing, syringes and dispenser connections. To remove air bubbles, refer to **Section 6.0** under Observed Problems.
3. Inspect for dried buffer salts or liquid buffer in and around all dispenser components. **Replace** as needed.

**Clean Waste/Wash Station**

Clean the waste/wash station by flushing it with approximately 20 mL of deionized water. Use a wide-mouth, unitary wash bottle for this procedure. Place the tip of the wash bottle into the waste/wash cup and flush thoroughly.

**Verify Unit Dose Probe Position**  
(if applicable)

Verify probe position daily at the completion of a unit dose run. If the puncture marks in the foil are not correct, refer to **Periodic Maintenance** section for unit dose probe positioning.



**Weekly Maintenance**

These procedures should be performed once a week. Record maintenance results as necessary in the maintenance log. Detailed instructions for each procedure are described in this section.

- Sample and Reagent Carousel Cleaning
- Dispenser Water Wash
- Air-Fan Filter Cleaning
- Photo Check (Test 2.2)

**Sample and Reagent  
Carousel Cleaning**


Inspect the carousels for dried buffer salts. Rinse with tap water as needed.

**CAUTION:** Do not wash the carousel with hot water because high temperatures may cause damage. Bleach solutions may also cause damage.

**Dispenser Water Wash**

1. Place the inlet tubing into deionized water.
2. Prime the system five times.
3. Replace the inlet tubing into the buffer container.
4. Prime the system five times.

**Air Fan Filter Cleaning**

1. Remove the base air-fan filter from the underside (front) of the TDxFLx<sup>®</sup> System by pulling straight out (toward the operator) on the filter handle.
2. Rinse the filter under running tap water. If a small vacuum is available, it may be used to clean the filter.
3. Blot the filter completely dry.
4. Allow the filter to dry 30 minutes before replacing it into your system.
5. Slide the filter back into the filter bracket with the  upright on the edge of the handle.
6. Slide the filter into the space brackets firmly until it comes to a stop. Check to ensure that the air-fan filter is properly seated and the handle is flush with the base of your system.

## Photo Check

The Photo Check procedure helps to ensure photometer/optical system reproducibility.

The X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel (LN 9520-31) is needed to perform this procedure. Use the same X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel for the Photo Check procedure that was used for the Photo Calibration procedure.

1. Press **TEST 2.2.1 DISPLAY**. Check that the gain value on the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label, located on inner wall of the carousel, agrees with the displayed value. If it does not, edit the parameter by pressing **EDIT** (enter carousel gain) **STORE STOP**. Also, print **Test 3.4** parameters by pressing **TEST 3.4 PRINT**. Edit them to agree with the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label, if necessary.
2. Lock the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel, and place it in the instrument. It may be necessary to insert an empty cuvette in any unused position of the carousel to keep it locked. Close the carousel access door.
3. Press **RUN** or alternately **TEST 2.2 RUN**, if the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel barcode label does not read correctly.
4. When the test is completed (approximately five minutes), the display returns to [READY]. An example of a typical photo check printout is presented on the following page.

PHOTO CHECK

DATE:

TIME:

SERIAL #:

GAIN:

LOC	INTENSITY	POL
1	10638.13	43.96
2	10543.19	46.73
3	10527.56	46.84
4	10647.67	47.13
etc.		

AVERAGE INTENSITY = 10580.61

INTENSITY RANGE = 315.35

AVERAGE POLARIZATION = 47.16

POLARIZATION RANGE = 0.89

Using the polarization and intensity values that are given on the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label, the photo check values should fall within the following specifications:

- Average Intensity =  $\pm 12\%$  of carousel labeled value
- Intensity Range =  $\leq 600$
- Average Polarization =  $\pm 1.5$  mP of carousel labeled value
- Polarization Range =  $\leq 2.5$  mP

Values outside the specified tolerance are flagged as errors. Refer to Photo Check out of Specification in [Section 6.0](#) under Observed Problems. Over a period of time, values will eventually trend out of specification due to normal component aging.



**Monthly Maintenance**

These procedures should be performed once per month. Record maintenance results as necessary in the maintenance log.

- Pipet Check (Test 2.3)
- Precision Dispenser Calibration
- Temperature Check (Test 2.1)
- Diluent Syringe Wash

## Pipet Check

This test checks the instrument's ability to perform linear pipetting, independent of chemistries. The pipet check resets the MN TR (.21) for each assay.

### Materials Needed

- Sample Carousel
- 20 X SYSTEMS<sup>®</sup> Sample Cartridges and Cuvettes
- Pipet Check Solution (LN 9531-02)
- Pipet with Tips or Disposable Pipet

### Procedure

1. Place 20 sample cartridges and cuvettes into the sample carousel.
2. Invert the pipet check solution two to three times to ensure mixing.
3. Pipette a minimum of 75 µL of the solution into each sample well.
4. Lock the carousel, place it into the instrument, and close the carousel access door.
5. Press **TEST 2.3 RUN**. The display reads:

PIPE CHECK

6. The test takes approximately fifteen (15) minutes. At the completion of a pipet check, if all values are correct, the intensity settings are stored. **DO NOT** press **STOP**, open the carousel access door, or otherwise terminate the check, until the display returns to [READY]. An example of a typical pipet check printout is shown below.

PIPE CHECK				
DATE:				
TIME:				
SERIAL #:				
REV. 1				
LOC	H	V	I	P
1	30.9	45.1	107.0	186.4
2	30.5	44.2	105.3	183.8
3	31.8	45.1	108.7	173.2
4	33.5	47.7	114.7	174.5
etc.				
-----				
REV. 2				
LOC	H	V	I	P
1	816.6	837.6	2471.0	12.6
2	848.5	869.9	2567.0	12.4
3	837.7	857.9	2533.4	11.9
4	846.3	867.4	2560.1	12.2
etc.				
-----				
GROUP	RNG	AVG	RNG	AVG
	P	P	I	I
1-5	0.92	12.22	96.02	2527.5
6-10	0.88	12.00	181.43	3825.7
11-15	0.83	11.98	174.45	5184.9
16-20	0.91	12.05	216.65	5841.38
RATIO #1 = 0.99				
RATIO #2 = 0.98				
RATIO #3 = 0.97				

7. Ratios 1, 2, and 3 should be between 0.95 and 1.05. The average intensity (AVG I) of Groups 16 through 20 must be greater than 4,000 and less than 10,000.

If the average intensity of Group 16 - 20 is less than 4,000, the error message **AVG I TOO SMALL** prints. If the value is greater than 10,000, the message **AVG I TOO LARGE** prints. If the range I value is greater than or equal to 250.00 for any group, **FAILED-RNG I OUT OF SPEC** prints.

If any ratio value is not within a range of 0.95 to 1.05, **ERROR** prints next to the ratio.

8. If values are out of specification, wash the probe, and repeat the check. If values remain out of specification, see Pipet Check Out of Specification in **Section 6.0** under Observed Problems.

During the pipet check, different amounts of solution are aspirated from the sample well. The first dispensing cycle adds only buffer to each cuvette. After this cycle, background readings are taken. During the second dispensing cycle, increasing volumes of pipet check solution are aspirated from each sample well (in groups of 5) and dispensed into the cuvettes with the buffer.

Background intensity readings taken during Revolution 1 are subtracted from the intensities measured during Revolution 2, and the results are printed under REV 2. These intensity readings are averaged for each group of 5 cuvettes. The average intensities for the last three groups of five should be 150%, 200%, and 300% of the average of Groups 1-5 if the pipetting is accurate. The instrument calculates three ratios to correct for this expected increase in intensity so each ratio should be  $1.00 \pm 5\%$ . These ratios are calculated as follows:

$$\text{Ratio \#1} = 1.5 \times \frac{\text{AVG (1 - 5)}}{\text{AVG (6 - 10)}}$$

$$\text{Ratio \#2} = 2.0 \times \frac{\text{AVG (1 - 5)}}{\text{AVG (11 - 15)}}$$

$$\text{Ratio \#3} = 3.0 \times \frac{\text{AVG (1 - 5)}}{\text{AVG (16 - 20)}}$$

**Precision Dispenser  
Calibration**Materials Needed

- Analytical balance
- Deionized water
- Small beaker

Procedure

1. Using an analytical balance with an accuracy of  $\pm 1$  mg, dispense a 200  $\mu$ L aliquot of deionized water into a small beaker and record its weight (W). Continue to dispense and record a total of 10 weights.
2. Reduce data by subtracting each recording from the subsequent recording

$$(W_i - W_{i-1} = W \text{ of aliquot})$$

to obtain each individual aliquot weight.

3. Calculate mean ( $\bar{x}$ ), standard deviation (SD), and % coefficient of variation (CV).

$$\%CV = SD \div \bar{x} \times 100$$

Calibration is verified if  $\bar{x} = 200 \pm 2$  mg and  $CV \leq 2.0\%$ .

4. If dispenser calibration is not within limits, repeat the calibration procedure. If the dispenser fails again, contact the **Customer Support Center**.

## Temperature Check

This test checks the operation of all temperature-control circuitry by measuring cuvette (with and without liquid), air, optics, and liquid heat block temperatures.

### Materials Needed

- Sample carousel
- Cuvettes

### Procedure

1. Place 20 empty cuvettes into a sample carousel.
2. Lock the cuvettes in place.
3. Place the loaded carousel into the instrument and close the carousel access door.
4. Press **TEST 2.1 RUN**. The display reads:

TEMP CHECK

5. When the test is completed (approximately 15 minutes), the display reads:

READY

**NOTE:** The operator may terminate the Temperature Check by pressing **STOP** after the IR COLD AND QUIET and IR COLD AND NOISY printout.

The remaining results, V/F/D, CUVETTE TMPS BEFORE HEATING, WATCH FOR HEAT LEAKS, and AIR OPTICS LIQBLK VDET are for factory and service use only.

EXPECTED RESULTS

TEMP CHECK  
DATE:  
TIME:  
SERIAL #

CUVETTES WARM AND EMPTY		
LOC	DEGREE C	TDET*
1	37.5	40.1
2	36.6	40.0
3	36.0	40.1
4	35.8	40.0

CUVETTES WARM AND EMPTY  
TDET\* between 39.7°C and 40.7°C.

SQUIRTING LIQUID

LOC	LIQ BLK
1	34.7
2	34.6
3	34.6
4	34.9*
H = 34.9*	
L = 34.6*	

SQUIRTING LIQUID  
H\* and L\* between 34.5°C and 35.5°C.

CUVETTE TMPS		
WITH LIQ		W/O LIQ
1	33.9	37.5
2	34.0	36.6
3	33.9	36.0
4	34.2	35.8

MEDIAN = 33.9\*  
RANGE = 0.3\*\*  
H = 34.1  
L = 33.8

CUVETTE TMPS WITH LIQ MEDIAN\*  
between 33.5°C and 34.5°C.  
RANGE\*\* less than or equal to 1.5.

V/F/D CHECK

GND MEDIAN = 2.3597  
H = 2.3597  
RANGE = 0.0000  
L = 2.3597

5V MEDIAN = 4.7267  
H = 4.7267  
RANGE = 0.0000  
L = 4.7267

V/F/D CHECK - For factory use only.

IR COLD AND QUIET

[1] IR GND MEDIAN =  
H =  
RANGE =  
L =

[2] IR DRK MEDIAN =  
H =  
RANGE =  
L =

IR COLD AND NOISY

[3] IR GND MEDIAN =  
H =  
RANGE =  
L =

[4] IR DRK MEDIAN =  
H =  
RANGE =  
L =

IR COLD AND QUIET,  
IR COLD AND NOISY,  
IR GND Medians, and  
IR DRK Medians should satisfy  
the following equations:

$$\frac{\text{MEDIAN (1)} - \text{MEDIAN (3)}}{\text{MEDIAN (1)}} \leq | 0.005 |$$

$$\frac{\text{MEDIAN (2)} - \text{MEDIAN (4)}}{\text{MEDIAN (2)}} \leq | 0.005 |$$

**Explanation of Printout**

Empty cuvettes are heated by the air heating system. The temperature of each cuvette is measured by the thermovoltaic detector and printed as DEGREES C under CUVETTES WARM AND EMPTY. The optics assembly temperature is measured by the optics thermistor and printed as TDET.

As the buffer is dispensed, temperature of the liquid heater is measured (after each dispense) and printed as LIQ BLK under SQUIRTING LIQUID.

When the dispensing is complete, the temperature of each buffer-filled cuvette is measured and printed as CUVETTE TMPS WITH LIQ. Previous readings taken when cuvettes were empty are printed as W/O LIQ.

The carousel then moves until there is no cuvette in front of the thermovoltaic detector. Ten readings are taken with the detector disabled (GND), and ten readings are taken with the detector enabled (DRK). The median, range, high, and low values are printed for each group. These readings are labeled IR COLD AND QUIET.

Next, the carousel rotates continuously and the same series of readings are taken and printed for each group. These readings are labeled IR COLD and NOISY. These readings check the thermovoltaic detector operation with no signal as well as the influence of any electrical noise generated by the carousel motor.



**Diluent Syringe Wash**

The diluent syringe wash removes buffer salt build-up from the inside of the syringe barrel.

Materials Needed

- Lint-free tissue
- Deionized water

Procedure

1. Refer to the Component Replacement section for instruction on **diluent syringe removal and replacement**.
2. Remove the diluent syringe from the analyzer and pull the plunger out.
3. Wipe the white tip with a lint-free tissue moistened with deionized water.
4. Place a finger over the LUER-LOK<sup>®</sup> end of the syringe, and fill the barrel with deionized water to rinse out the syringe interior. Repeat this step several times.
5. Reassemble and reinstall the syringe.



**Periodic Maintenance**

These procedures should be performed on a periodic basis as required.

- Barcode Reader Cleaning
- Boom-Arm Barcode Reader DAC Adjustment Check
- Boom-Arm Barcode Reader Adjustment on Sample Carousel
- Buffer Platform Adjustment
- Carousel Home Sensor Cleaning
- Circuit-Board Cleaning
- Optical and Thermal Sensor Cleaning
- Automated Probe Decontamination
- Probe-Positioning Check and Adjustment Procedure

**Quarterly Maintenance**

- Impact Printer (Cleaning and Lubrication)
- TDx<sup>®</sup> Centrifuge RPM Check

**Barcode Reader  
Cleaning****Boom-Arm Barcode Reader**

1. Moisten a cotton swab with deionized water, and blot the swab to remove excess water.
2. Gently wipe the lens on the underside of the boom-arm barcode reader to remove any dirt or dried buffer. Dry the barcode reader with another swab.
3. Repeat the cleaning if necessary.

**Reagent Carousel Barcode Reader**

1. Moisten a cotton swab with deionized water, and blot the swab to remove excess water.
2. Gently wipe the outer surface of the reagent barcode reader to remove any dirt or dried buffer. Dry the reader with another swab.
3. Repeat the cleaning if necessary.

## Boom-Arm Barcode Reader DAC Adjustment Check

This procedure adjusts the DAC (Digital/Analog Converter) setting to optimize the ability of the analyzer to read barcode labels on batch reagent packs.

Do not perform this test unless instructed to do so by the **Customer Support Center**.

### Materials Needed

- **Batch-pack adapter**
- Three batch reagent packs with barcode labels that are clean, undamaged, and properly seated.

### Procedure

1. Ensure that the DAC parameter of the analyzer is set to the starting value of 100 as follows:
  - a. Press **SYSTEM 3.10 EDIT**.
  - b. If the DAC value is 100, press **STOP**, and continue to step 2.
  - c. If not, press **100 STORE STOP** to edit the value.
2. **Install the batch-pack adapter** as detailed in **Section 3.0**.
3. Select one reagent pack, and remove the vial caps.
4. Place the reagent pack into the instrument.
5. Press **TEST 4.4 RUN** to activate hand controls of the boom arm movement.
6. Press **RUN** to initiate the auto-DAC test.
7. Observe the printout.

DAC values print sequentially, ranging from 100 to 255.

Next to each DAC value, the printout indicates whether or not the system was able to read the barcode label at that DAC setting:

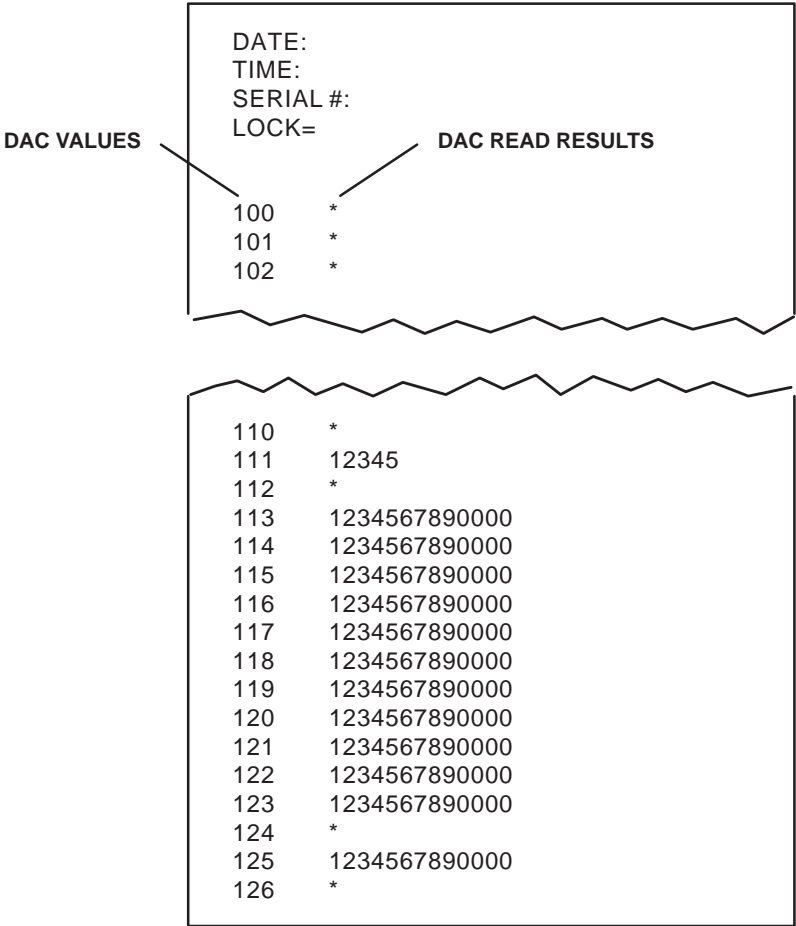
- *Successful* reads are indicated by the 13-digit number matching the barcode label.
- *Failed* reads are indicated by either an asterisk (\*) or a 1 to 12-digit number.

In order to calculate the optimal DAC setting, it is beneficial to know the full range of DAC values exhibiting successful reads on the analyzer.

On the printout, the full range of successful reads is included with a block of DAC values:

- a. Beginning with failed reads
- b. Continuing with a series of 10 or more successful reads
- c. Ending with failed reads

As a result, the *initial DAC reading(s)* on the printout *should fail*.



8. Check the DAC read result when the DAC value = 100.
- a. If the reading *failed*, allow the test to continue to completion. Go to **step 9**.
  - b. If the reading was *successful*, reduce the DAC setting by 10 units (moving back the starting point for the auto-DAC test).
    - The auto-DAC test may be interrupted by pressing **STOP**.
    - Press **SYSTEM 3.10 EDIT 90 STORE STOP**.

**Repeat steps 5-7** with the new DAC setting. Check the initial read on the printout.

If necessary, continue editing **System 3.10** to lower values until the initial read fails.

9. Press **STOP**, remove the reagent pack, and replace the vial caps.
10. Identify the largest range of consecutive successful reads on the final printout.

The largest range of successful reads should be greater than or equal to 10. If not, try a different reagent pack. If the range of the second pack is less than 10, call the **Customer Support Center** with details.

11. Record the minimum and maximum DAC values indicating successful reads for the largest range.
12. Calculate the optimal DAC setting for the reagent pack:

$$\text{Optimal DAC setting} = \frac{\text{minimum DAC} + \text{maximum DAC}}{2}$$

$$\text{For the example printout, } \frac{113 + 123}{2} = 118$$

13. Repeat steps 3-8 using the two additional batch reagent packs.
14. Calculate the average optimal DAC setting for the three reagent packs. This value is the optimal DAC setting for the analyzer.
15. Store the optimal DAC setting in the analyzer:
  - Press **SYSTEM 3.10 EDIT**.
  - Enter the value calculated in step 14.
  - **STORE STOP**.

### Boom-Arm Barcode Reader Adjustment on Sample Carousel

#### Materials Needed

- **Batch-pack adapter**
- Calibration carousel
- Batch reagent pack

#### Procedure

1. Install the **batch-pack adapter**.
2. Place a calibration carousel into the instrument. (Place a batch reagent pack with the vial caps removed into the instrument.)
3. Press **SYSTEM 3 PRINT** to print **System 3** parameters.
4. Press **TEST 4.1 RUN**.
5. Press **9 PRIME**. The boom-arm barcode reader scans the calibration carousel label. The display reads [BAR AMPL] followed by a number and alternates with the number on the calibration carousel label.

If the calibration carousel label is read correctly and the BAR AMPL is 20 or greater, press **STORE STOP** to return the instrument's boom arm home and the instrument to [READY]. If the calibration carousel number is not read correctly, perform the following:

- a. Record the BAR AMPL value.
  - b. Press **STORE** to move the boom arm home.
  - c. Place a sample carousel into the instrument, and read the label by pressing **PRIME**.
  - d. Proceed with the steps below that apply to the results observed.
6. If the problem occurs with only one sample carousel remove the label and put a new label on that carousel.
  7. If the BAR AMPL reading is less than 20 on the sample carousel and the carousel is being read incorrectly, proceed as follows:
    - a. Press **STORE** to home the R-boom.
    - b. Place the calibration carousel into the instrument.
    - c. Turn the barcode reader on by performing the following steps:
 

Press the **CLEAR** key twice, [S=XXX R=XXX B=X] (X equals a displayed character) appears in the display.

Key in the value from **System 3.10**, then press the **DISPLAY** key.

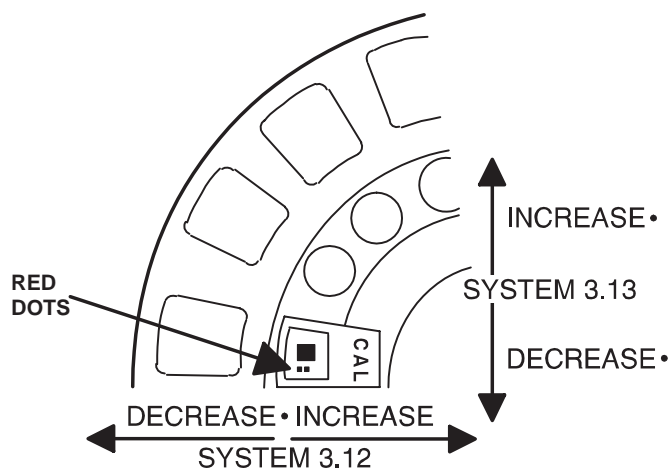
Position a small sheet of white paper, approximately 1/4" below the barcode reader lens of the boom arm.

Press the **PRIME** key until a small red light is projected on the paper.

Press the **NEXT** key twice, [HC=X C=X S=XXXX] (X equals a displayed character) appears in the display.
    - d. Press **9** then **STORE** to home the boom.
    - e. Press **7, 0** to home the carousel.
    - f. Press **7** until [TB = 2] appears in the display, then press **1** repeatedly until [TB=20] appears in the display.
    - g. Press **7** then **1** or **4** until [S=] shows the same step number as **System 3.13**.
    - h. Press **9** until [TB = 1] appears in the display.
    - i. Press **6** until the boom-arm barcode reader is near the calibration carousel.
    - j. Press **9** until [S=] appears in the display then press **6** or **3** as needed until [S=] shows the same step number as **System 3.12**.



8. The red dots should be clearly visible in front of the barcode as shown below and should be approximately centered left to right. (The barcode-reader dots may not be in the same horizontal orientation as shown.)



BARCODE-READER ORIENTATION

If the red dots are not centered, press **6** to move the reader to the right or **3** to move the reader to the left until the dots are centered. Record the step number [S=] showing on the display. At the completion of this procedure, **System 3.12** should equal this value plus or minus two steps. If it does not, edit **System 3.12** to the correct value by performing Step 9.

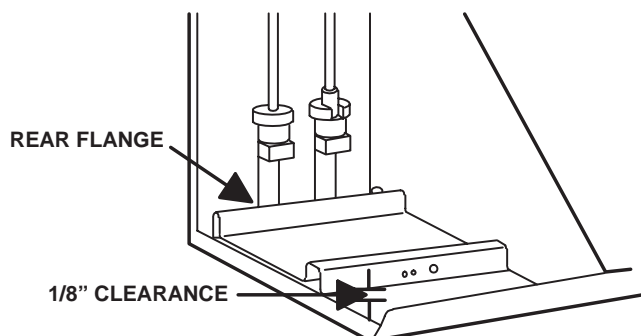
To find the step number where the barcode reader detects the transition from white to black on the barcode label, proceed as follows:

- a. Press **7** twice until [S=] appears in the display.
  - b. Press **4** once to move the carousel counterclockwise one step.
  - c. Press **9** and note whether [R=B]. If [R=W], press **7**, **4** and **9** in sequence until [R=B].
  - d. When [R=B], press **7**.
  - e. **System parameter 3.13** should be 4 to 9 steps less than the step number [S=] showing when [R=B] showed in the display. If it is not, edit **System 3.13** to the correct value by performing Step 9.
9. To edit **System 3.12 or 3.13** parameters perform the following steps:
    - a. Press **STOP SYSTEM 3.XX EDIT** (enter the step number).
    - b. Press **STORE STOP**.
  10. If an adjustment has been made, check for proper operation of the boom-arm barcode reader by **repeating Steps 4 and 5** for all carousels.
  11. Press **STORE STOP** to return the boom arm to the home position and return the instrument to [READY]. It is not necessary to perform any calibration procedures.

## Buffer Platform Adjustment

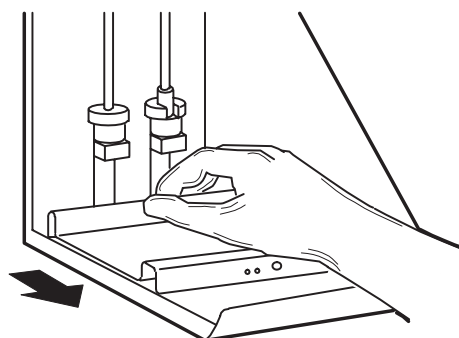
The following paragraphs detail the procedure for adjusting the buffer platform so that the buffer sensor properly detects the volume of buffer present.

1. Lift the buffer access door. Lift the buffer container off the platform and set it to the side of the instrument.
2. A clearance of 1/8" should be present between the base of the analyzer and the lower front edge of the buffer platform as shown below.
3. To increase the clearance, push back on the rear flange of the buffer platform until there is approximately 1/8" clearance when the platform is released and comes to rest.



INCREASE BUFFER PLATFORM CLEARANCE

4. To decrease the clearance, pull forward on the rear flange of the buffer platform as shown below until there is approximately 1/8" clearance when the platform is released and comes to rest.



DECREASE BUFFER PLATFORM CLEARANCE

5. To verify the proper positioning of the platform, place a buffer container with approximately 100 mL of buffer on the platform and press **TEST 4.3 RUN 9**. If the display reads [B=N], the platform is adjusted properly. The display should change to [B=Y] when buffer is added to the container. It is not necessary to perform any instrument calibration procedures.

### Carousel Home Sensor Cleaning

#### Sample Carousel

1. Locate the sample-carousel home sensor in the baseplate at the 9 o'clock position.
2. Blow forced air (canned air, tubing from a laboratory air outlet, etc.) into the sensor to dislodge the dirt and lint particles.

#### Reagent Carousel

1. Locate the reagent-carousel home sensor in the baseplate at the 12 o'clock position from the reagent carousel post.
2. Blow forced air (canned air, tubing from a laboratory air outlet, etc.) into the sensor to dislodge the dirt and lint particles.

### Circuit-Board Cleaning

#### Materials Needed

- Lint-free tissue
- Methanol

#### Procedure

1. Turn the instrument off, and unplug the unit from the wall outlet.  
**DANGER:** ALWAYS have the power off and the unit unplugged before removing the rear access panel.
2. Remove the printed circuit board (PCB) according to the instructions in the **Component Replacement** section under Circuit Board Removal and Replacement.
3. Moisten a lint-free tissue with methanol, and wipe the metal contacts on the edge of the board.  
**NOTE:** DO NOT use alcohol preps for this procedure.
4. Allow the methanol to evaporate.
5. Insert the printed circuit board (PCB) according to the instructions in the **Component Replacement** section under Circuit Board Removal and Replacement.

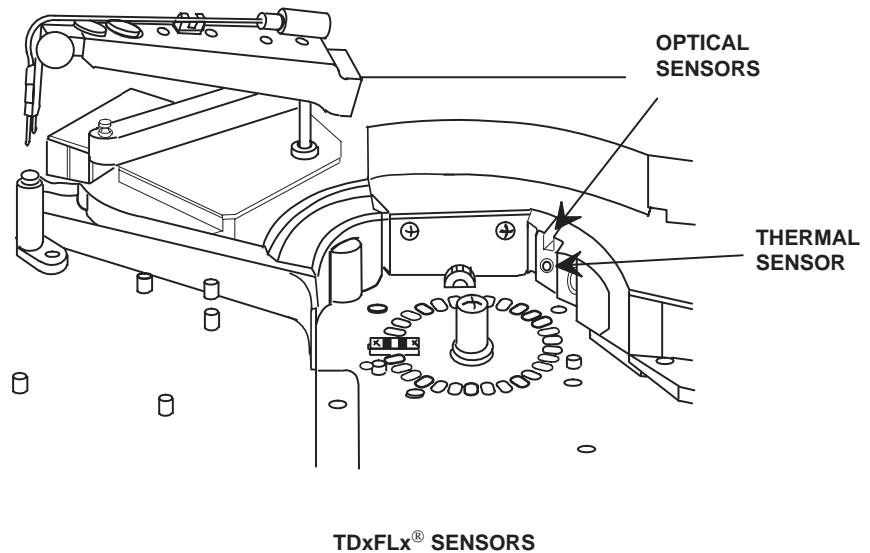
### Optical or Thermal Sensor Cleaning

#### Materials Needed

- Cotton swab
- Deionized water

#### Procedure

1. Moisten a cotton swab with deionized water, and blot the swab to remove excess water.
2. Locate the optical and thermal sensors as indicated below.
3. Gently clean the sensors with the moist cotton swab.
4. Visually inspect the sensors for cleanliness.
5. Repeat this procedure as necessary.



Automated Probe  
Decontamination

The probe must be decontaminated prior to servicing or removing. A 1% sodium hypochlorite solution (household bleach diluted to 20%) has been shown to inactivate infectious agents such as HIV and Hepatitis B.

Materials Needed

- Sample carousel
- 2 Cuvettes
- 1% sodium hypochlorite solution
- Deionized water
- Pipet

Procedure

1. Insert the cuvettes into positions 1 and 2 on the sample carousel. Lock the carousel.
2. Pipet 3 mL of 1% sodium hypochlorite solution into position 1.
3. Pipet 3 mL of deionized water into position 2.
4. Place the sample carousel into the instrument.

Step	Operator Action	System Response
A	Press <b>TEST 6.8 RUN</b>	<div>PROBE DECONTAM</div> <div>TIME LEFT: XX:XX</div> <div>15 minute countdown</div> <div>PROBE DECONTAM</div> <div>Prime</div> <div>DONE</div>
B	Press <b>STOP</b> . Remove the carousel and discard the cuvettes.	<div>READY</div>

**NOTE:** If the **STOP** key is pressed any time during the decontamination process the system will prime and return to the [READY] state.

Probe-Positioning  
Check and Adjustment  
Procedure

Random Access and Batch

To ensure the highest level of performance from the TDxFLx<sup>®</sup> System, it is extremely important that the probe be precisely positioned. The following is a step-by-step procedure to check and adjust the probe position in order to optimize system performance in the random access and batch modes of operation.

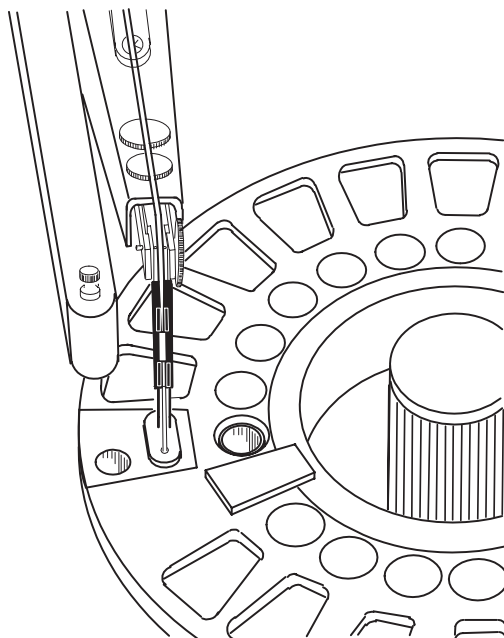
Materials Needed

- Sample carousel
- Batch probe-positioning cartridge

Procedure

1. With the probe-positioning cartridge in Location 1, place the carousel in the instrument. Leave the access door open. Press **SYSTEM 3 PRINT**.
2. Use hand controls (steps A-E) to check the probe position in the predilution well.

Step	Operator Action	System Response	Display
A	Press <b>TEST 4.4 RUN</b>	Activates test	HR=H R=W S=X
B	Press <b>TEST</b> once	Positions probe above probe-positioning cartridge	HR=N R=W S=XXX
C	Press <b>9</b>	Changes to Z-boom control	HZ=N L=N TB=X
D	Press <b>9</b>	Changes to step function	HZ=N L=N S=XX
E	Press <b>6</b> (Repeat as necessary until the probe tip enters the opening at predilution well.)	Lowers probe toward probe-positioning cartridge	HZ=N L=N S=XX



3. If the probe is properly positioned, the probe tip should enter the opening in the probe-positioning cartridge to the most forward point without moving the cartridge. If the positioning is correct, return the boom to its home position by pressing **STORE, 7, 0**, then **STOP**.
4. If the probe is not properly positioned left to right, press **STORE, 7, 7**, and **4** or **1** to reposition left to right. (4 moves right by steps and 1 moves left by steps).

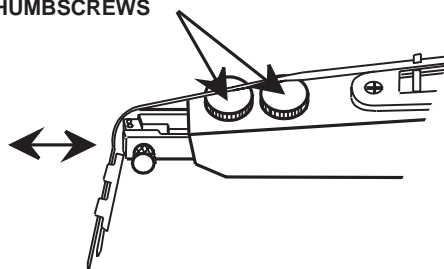
When the R-Boom is centered over the predilution well opening, record the step number indicated on the display [HR=N R=W S=XXX]. Repeat **Step 2 C, D, and E**. If the probe enters the opening without moving the cartridge, press **STORE, 7, 0, STOP**.

Edit the **System 3.4** parameter to the new value by pressing **SYSTEM 3.4 EDIT** and entering the new R-Boom step number, then **STORE, STOP**.

If the probe needs front-to-back adjustment, continue with **Step 5**.

5. If the probe is not positioned properly front-to-back (the probe moves the cartridge, or is positioned so it will not enter the opening), make the necessary front-to-back position adjustments as follows:
  - a. Supporting the underside of the boom to avoid damaging the probe tip, carefully loosen the two knurled thumbscrews on top of the boom arm 1/8 to 1/4 turn.
  - b. Move the probe holder into or out of the boom arm as needed to position the probe in the forward portion of the probe-positioning cartridge opening.
  - c. Supporting the underside of the boom arm, holding the probe securely in place, tighten the two knurled thumbscrews to secure the probe.

THUMBSCREWS



- d. To verify that the proper front to back adjustment was obtained, press **7** then **TEST**.
  - e. Repeat Steps 2 D and E.
6. Press **STORE**, **7**, **0**, then **STOP**.
7. Edit **System 3.4** if required.

To verify that the proper probe alignment was obtained, repeat the **probe-positioning procedure Step 2 A-E**. If another adjustment is required, follow **Step 3** and verify positioning by performing **Step 2** again.
8. When the verification is complete, press **STORE**, **7**, **0**, then **STOP**.
9. Perform a batch boom calibration (**Test 3.2**).
10. Perform a reagent carousel calibration (**Test 3.13**).
11. Perform a 4-pot reagent pack boom calibration (**Test 3.7**), if applicable.



Unit Dose

To ensure the highest level of performance from the TDxFLx<sup>®</sup> System, it is extremely important that the probe be precisely positioned. Positioning is especially important for the predilution well, the sample well, and the three foil-covered reagent wells. The following is a step-by-step procedure to check and adjust the probe position in order to optimize system performance in the unit dose mode of operation.

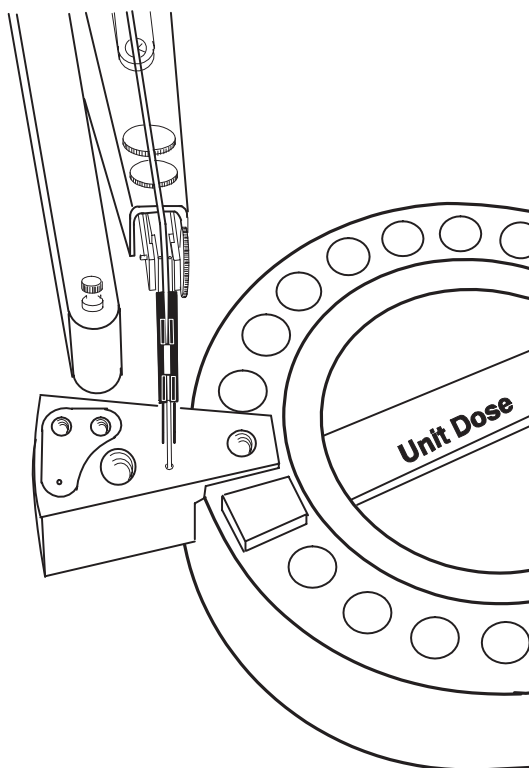
Materials Needed

- Unit dose carousel
- Unit dose probe-positioning cartridge

Procedure

1. Place the unit dose probe-positioning cartridge into location #1 of a unit dose carousel. Place the carousel into the instrument. Leave the access door open. Press **SYSTEM 3 PRINT** and **SYSTEM 8 PRINT**.
2. Use the following steps to check the probe position in the predilution well.

Step	Operator Action	System Response	Display
A	Press <b>TEST 4.4 RUN</b>	Activates test	HR=H R=W S=9
B	Press <b>TEST</b> once	Positions probe above probe-positioning cartridge	HR=N R=W S=XXX
C	Press <b>9</b>	Changes to Z-boom control	HZ=N L=N TB=X
D	Press <b>9</b>	Changes to a step function	HZ=N L=N S=XX
E	Press <b>6</b> (Repeat as needed)	Steps the probe down until the probe is several steps from touching the top or entering the cartridge opening in the predilution well.	HZ=N L=N S=XX



3. If the probe is properly positioned, the probe tip should enter the opening in the probe-positioning cartridge to the most forward point without moving the cartridge. If the positioning is correct, press **STORE, 7**, then proceed to **Step 7**.
4. If the probe is not properly positioned left to right, press **STORE, 7, 7**, and **4** or **1** to reposition left to right. (4 moves right by steps and 1 moves left by steps).

When the R-Boom is centered over the predilution well opening, record the step number indicated on the display [HR=N R=W S=XXX]. Repeat **Steps 2C through E**. When the correct R-boom step number has been determined, press **STORE, 7, 0, STOP**.

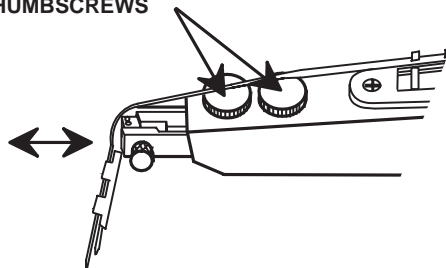
Edit the **System 3.4** parameter to the new value by pressing **SYSTEM 3.4 EDIT** and entering the new R-Boom step number, then **STORE, STOP**.

Repeat **Steps A-E**. If the probe is positioned properly front-to-back, press **STORE, 7**, then proceed to **Step 7**.

**NOTE:** If the probe is not positioned properly front-to-back (the probe moves the cartridge, or is positioned so it will not enter the opening), make the necessary front-to-back position adjustments as follows:

- a. Support the underside of the boom to avoid damaging the probe tip. Carefully loosen the two knurled thumbscrews on top of the boom arm 1/8 to 1/4 turn.
- b. Move the probe holder into or out of the boom arm as needed to position the probe in the forward portion of the cartridge opening.
- c. Supporting the underside of the boom arm, hold the probe securely in place, and tighten the two knurled thumbscrews to secure the probe.

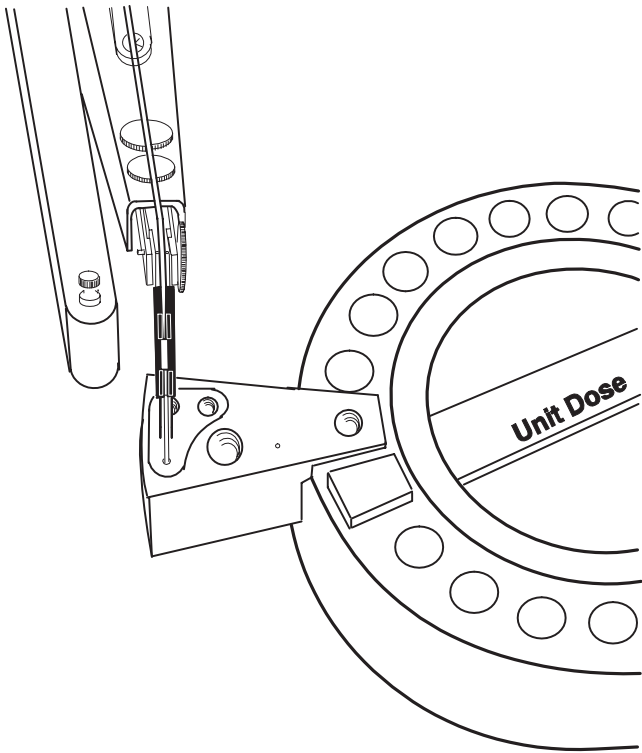
THUMBSCREWS



5. To verify that the proper front-to-back probe alignment was obtained, repeat the **positioning procedure Step 2 A-E**. If another adjustment is required, follow **Step 4** then verify positioning by performing **Step 2** again.
6. When the adjustment and subsequent verification are completed, press **STORE 7** to home the Z-boom. Proceed to **Step 7**.

7. Perform Steps F-J to check the unit dose probe-positioning cartridge in the T well of the unit dose probe-positioning cartridge:

Step	Operator Action	System Response	Display
F	7 (as necessary)	Ensures step function is active	S = XXX
G	4 (move right) 1 (move left)	Adjusts the left-to-right position of the probe until it is aligned with the hole in the T well. Adjust until [S= XXX] in the display is the same as the <b>System 8.4</b> parameter for your instrument. Refer to the <b>System 8 printout obtained in Step 1.</b>	
H	9	Changes to Z-boom control	HZ=H L=N TB=1
I	9	Changes to step function	HZ=H L=N S=XX
J	6 (repeat as necessary)	Steps the probe down until it is several steps from touching the top or entering the cartridge opening in the T well.	



8. If properly positioned, the probe tip should enter the opening in the T well of the unit dose probe-positioning cartridge without moving the cartridge.

If the positioning is correct, return the boom home by pressing **STORE, 7, 0**, then **STOP**. Proceed to Step 9.

If the probe is not properly positioned left-to-right, press **STORE, 7** (twice), and **4** or **1** to reposition left-to-right. Note the [S= ] number in the display when the R-boom is centered over the T well. If another adjustment is required, repeat the procedures in this paragraph. **Repeat steps H, I, and J.**

**NOTE:** The **System 8.4** parameter can be edited when adjustments are complete by pressing **SYSTEM 8.4 EDIT**. Enter the new R-boom step number (recorded above) and press **STORE**. Press **STOP** to return to [READY].

If the probe hits in front of or behind the opening, the positioning is not correct. Contact the **Customer Support Center**.

9. Perform a batch boom calibration (**Test 3.2**).
10. Perform a reagent carousel calibration (**Test 3.13**).
11. Perform a unit dose boom calibration (**Test 3.6**), if applicable.
12. Perform a 4-pot reagent pack boom calibration (**Test 3.7**), if applicable.

### Impact Printer (cleaning and lubrication)

Do not perform this procedure on the thermal printer. Remove the printer access door and assure your TDxFLx<sup>®</sup> System has an impact printer as illustrated below.

#### Materials Needed

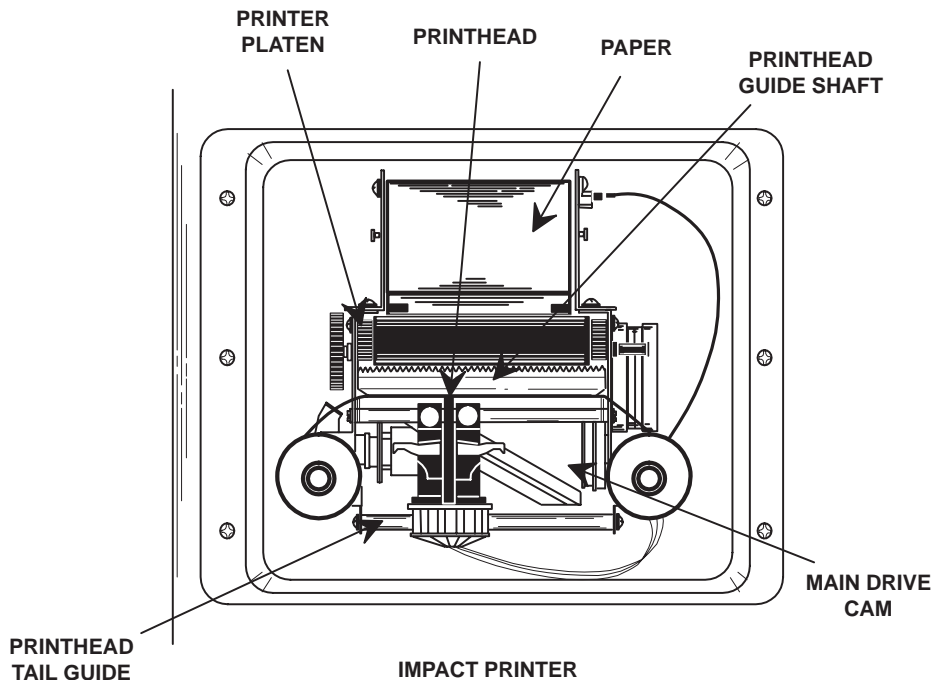
- Clean cloth
- Isopropanol
- Cotton swab
- Grease (LN 9518-14)

#### Cleaning

1. Wipe the printhead guide shaft with a clean cloth dampened with isopropanol.
2. Clean the old lubricant from the slot in the main drive cam and from the slot in the printhead tail guide with a cotton swab dampened with isopropanol. Move the printhead to clean both slots completely.

**CAUTION:** To expose the underside of the cam, rotate the cam toward the platen to avoid damage.

3. Rotate the printer platen by moving it toward the rear of the printer.
4. Clean the platen with a cloth dampened with isopropanol.



#### Lubrication

1. Apply a light coating of lubricant to the printhead guide shaft, the main drive cam slot, and the slot in printhead tail guide.
2. To distribute lubricant, press **TEST 5.4.1 RUN**.

TDx<sup>®</sup> Centrifuge  
RPM Check

Reference [Appendix B](#) for information.





**Component Replacement**

This section details the procedure for replacing various TDxFLx<sup>®</sup> Components. If any of these procedures necessitate a power interruption of 30 minutes or more, the instrument must be allowed to warm up for 30 minutes after power is restored. Failure to do so may result in heater error messages.

- [Buffer Replacement](#)
- [Circuit Board Removal and Replacement](#)
- [Lamp Replacement](#)
- [Impact Printer Paper and Ribbon Installation/Replacement](#)
- [Thermal Printer Paper Installation/Replacement](#)
- [Probe/Fluid-Sensing Electrode Replacement](#)
- [Syringe Replacement](#)
- [Tubing Replacement](#)
- [Valve Block Replacement](#)

**Buffer Replacement**

If there is insufficient buffer to start an assay, the display reads:

BUFFER EMPTY

When this condition occurs, replace the buffer as detailed below.

1. Press **STOP**.
2. Lift the buffer access door on the left side of the instrument.
3. Twist off the buffer cap with the tubing attached; remove and discard the empty buffer bottle. Use care to avoid crimping the inlet tubing when you remove the bottle.
4. To avoid possible contamination do not combine contents of different bottles.
5. Replace the cap and tubing on a full X SYSTEMS<sup>®</sup> Dilution Buffer bottle, and set it into position. Verify that the waste container is in position, then press **PRIME**.
6. Press **PRIME** five times to eliminate any trapped air bubbles. Refer to the procedure on air bubble removal if necessary, in [Section 6.0 Troubleshooting](#), under Observed Problems.
7. Close the buffer access door.

**Circuit Board Removal and Replacement**

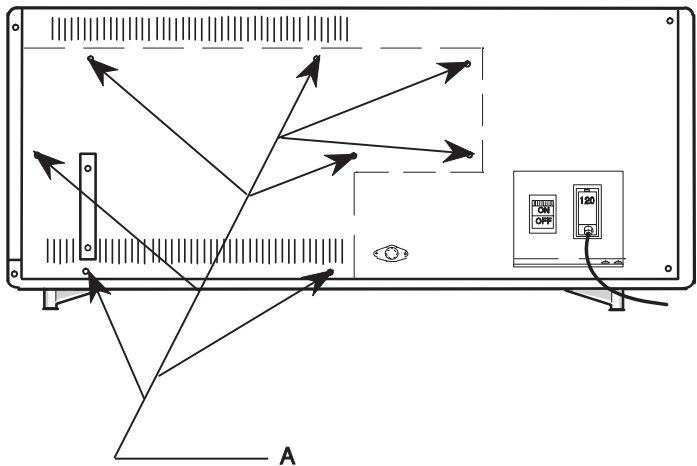
This procedure describes the steps necessary to remove, and replace a printed circuit board (PCB).

Removal

1. Turn TDxFLx<sup>®</sup> System power off, and unplug the unit from the wall outlet.

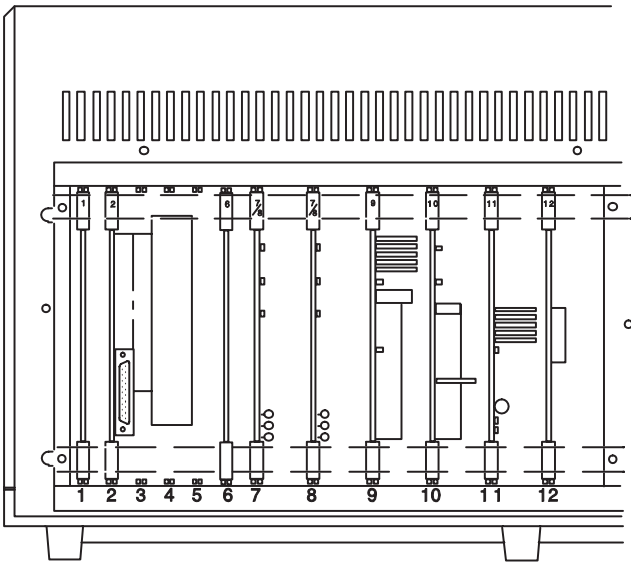
**DANGER:** ALWAYS have the power off and the unit unplugged before removing the rear access panel.

2. Remove the screws labeled (A). The rear panels have eight screws.



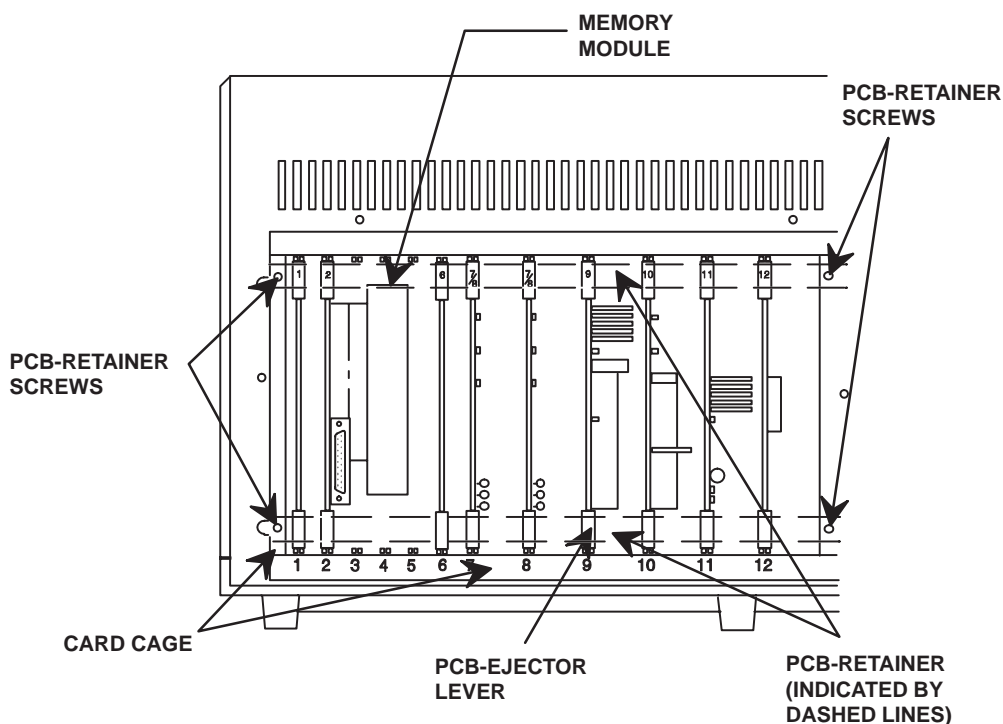
BACK PANEL

3. Remove the plate to allow access to the card cage. PCB card slots are numbered from 1 on the left to 12 on the right as shown below.



CARD CAGE

4. Determine if PCB retainer(s) (silver bars that attach to the card cage, over the PCB-ejector levers) are installed in the analyzer.
  - If **not present**, continue to step 5.
  - If **present**, remove them before continuing as follows:
    - a. Remove the PCB-retainer screws.
    - b. Remove the PCB-retainer(s).
    - c. Discard the PCB retainer and screws.



**NOTES:** Slots 3, 4 and 5 are empty.

To remove memory module from PCB #2, remove PCB #2 from card cage. Loosen thumbscrews on the top of the memory module. Module can then be separated from the PC board.

When installing the memory module, ensure that the module is held securely by the retaining clip and that the thumbscrews are finger-tight.

The TDxFLx<sup>®</sup> System will not power on if the rear panel has not been reinstalled properly.

5. To remove a PCB, simultaneously lift up on the top lever and push down on the bottom lever. When the PCB has been loosened, pull it completely free of the card cage. To prevent an accidental mix-up, **do not** remove more than one PCB at a time. If only the reseating of a PCB is necessary, do not pull the board completely free of the card cage.

### Replacement

1. To install a PCB, orient the PCB so that the components are on the right side as the board is inserted into its card-cage slot.
2. Insert the PCB into the correct slot, ensuring that the numbers match. The number on the ejector lever should match the number on the card cage.
3. Ensure that the top and bottom edges of the PCB are in the guides.
4. To seat the PCB in the card-cage connector, simultaneously press firmly on the top and bottom levers until a distinct click is heard.
5. Replace the rear panel and install the screws. No instrument calibration is required after performing this procedure.

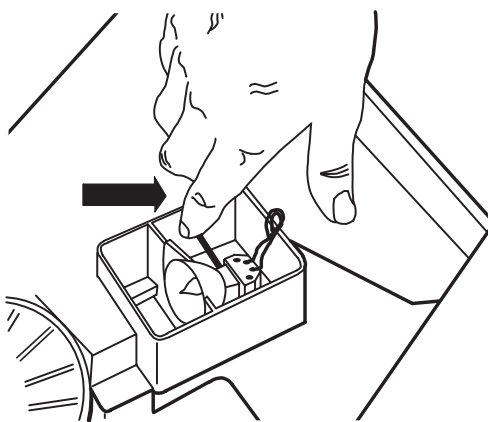
## Lamp Replacement

To replace the lamp, use the procedure listed below.

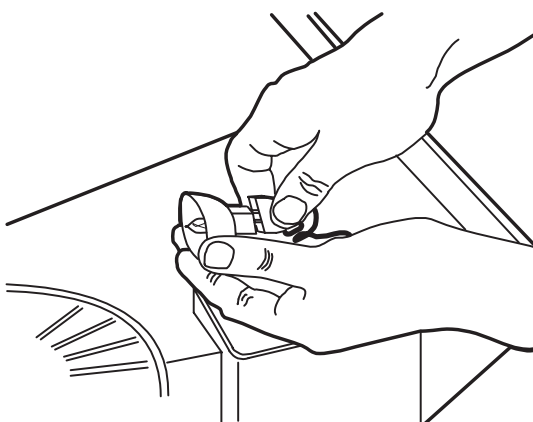
**CAUTION:** Use the designated lamp (LN 9520-12) from Abbott Laboratories. Use of any other lamp may adversely affect assay results.

1. Open both the carousel-access door and the reagent-display door and remove the lamp cover. Note how the lamp is positioned in the housing.
2. Push the lamp ejector bar to the right and lift the lamp out of the housing.

**CAUTION:** The lamp may be very hot.



3. Unplug the lamp from the lamp holder.



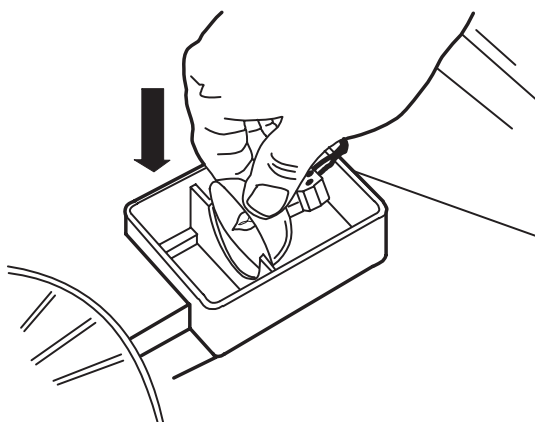
4. Inspect the contacts on the new lamp. Clean the contacts with emery cloth or sandpaper if there is evidence of corrosion.

- Using a lint-free cloth, grasp the new lamp by the small inner bulb and insert the prongs into the socket.



**NOTE:** The base of the lamp is made of ceramic that can crack if pressure is applied improperly. By holding the inner bulb firmly, the possibility of cracking the ceramic is minimized.

- Seat the lamp down firmly in the lamp housing. Ensure that the lamp ejector bar returns to the left and that the face of the lamp is parallel to the lamp housing wall.



- Place the connecting wires through the notch on the right side of the lamp housing.
- To check the operation of the lamp, press **TEST 4.2 RUN PRIME**. The source lamp should light. Press **STOP** to return to [READY]. If the lamp does not light, replace it with another new lamp ensuring that the contacts are clean and the filament is not broken (**Steps 2-8**).
- Replace the lamp cover securely on the lamp housing to prevent stray light.

## Impact Printer Paper and Ribbon Installation/Replacement

### Paper Replacement

1. Lift the printer access door and remove the empty paper roll from the bracket at the rear of the printer.
2. Insert the plastic spindle into a new paper roll.
3. Place the roll into the carriage with the paper feeding from the back and under the bottom of the roll.
4. Thread the paper under the cutter bar, and set the movable paper guides so that they are just touching the edges of the paper. Be sure that the paper guide tabs (if present) are placed on top of the paper.
5. Close the printer access door.

**NOTE:** Check to see that the paper is free to advance through the cover.

6. Advance the paper one line at a time by pressing **PRINT**.
7. Press **TEST 5.4.1 RUN** to check the operation of the printer. Press **STOP** to return to [READY].

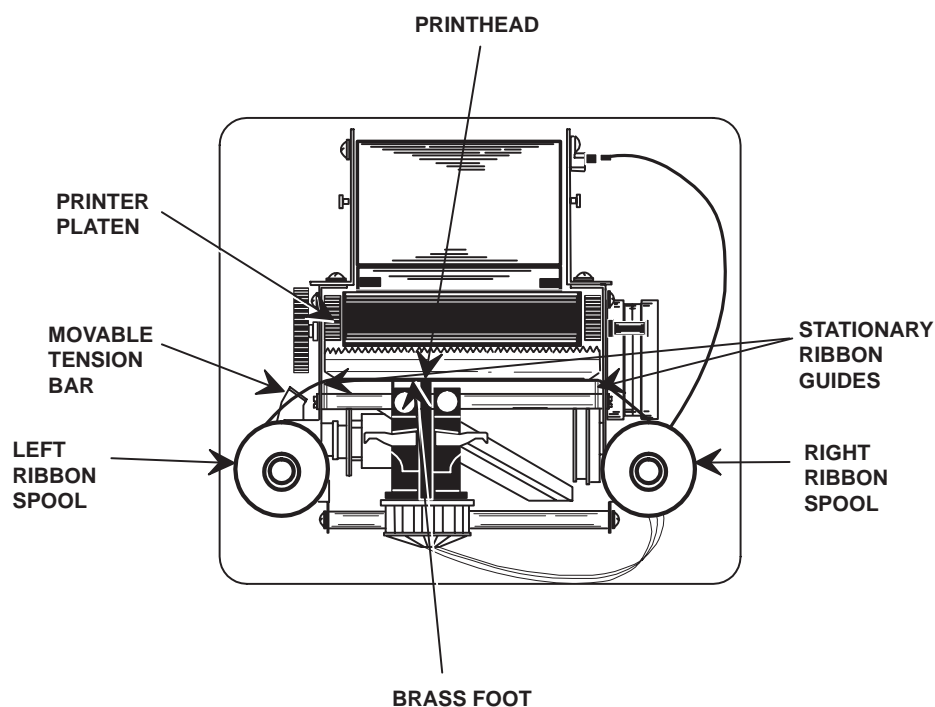
**NOTE:** A 3 7/8-inch roll of replacement paper may be purchased at most stationery supply stores. (Use paper with a rough texture for best results, or order from Abbott using LN 9520-20.)

### Ribbon Replacement

1. Lift the printer access door. Note how the ribbon is threaded. Remove the used ribbon spools.
2. Insert the new spools, teeth down, onto the ribbon spindle. Place the blue spool on the left and the white spool on the right.



3. Thread the ribbon as indicated in the printer illustration. The ribbon should pass:
  - a. Right of the movable triangular tension bar
  - b. Behind the ribbon guide at the left end of the printer
  - c. On top of the brass foot
  - d. Between the printhead and the paper
  - e. Behind the ribbon guide at the right end of the printer
  - f. Onto the right ribbon spool
4. Remove the slack in the ribbon by turning the right ribbon spool (white) clockwise.
5. To check proper installation, press **TEST 5.4.1 RUN**. Press **STOP** to return to [READY].
6. As you close the printer access door, feed the paper through paper slot on the door and ensure that the paper is free to advance.



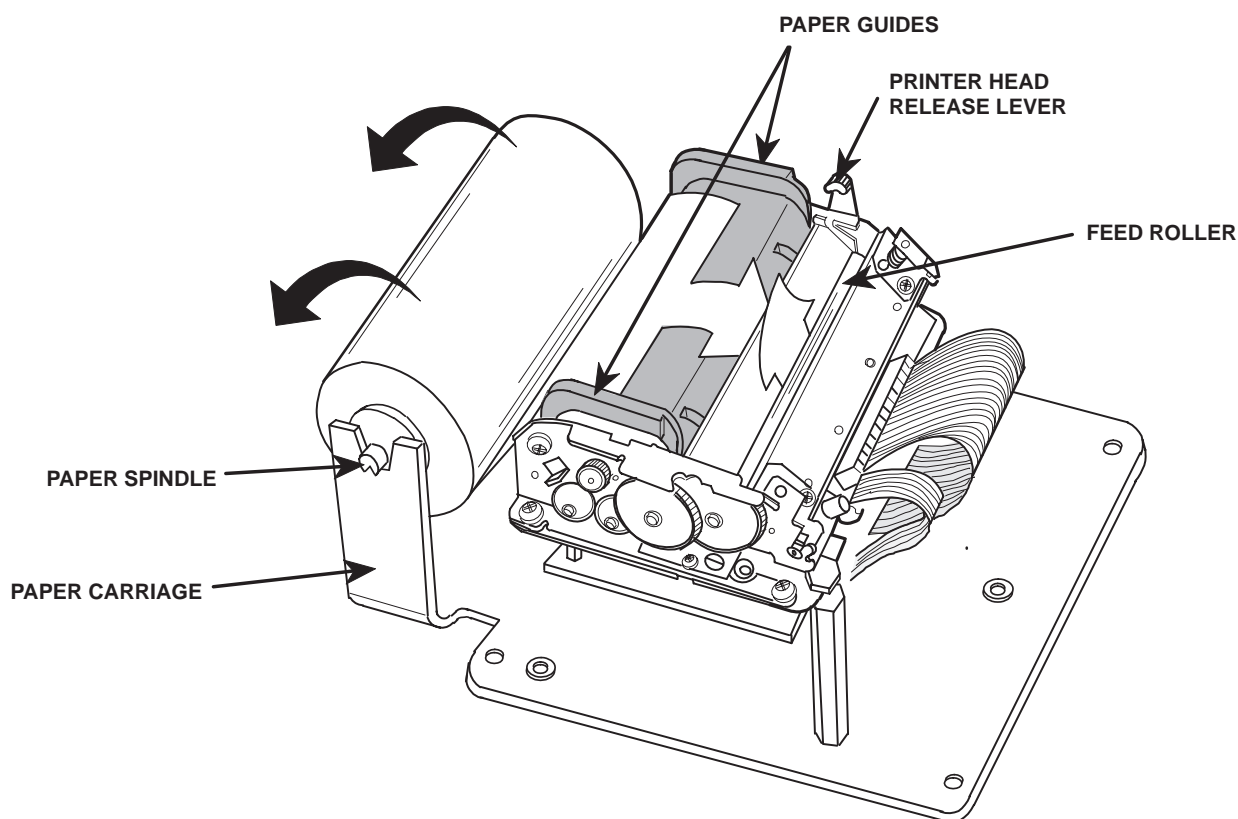
PRINTER RIBBON REPLACEMENT

### Thermal Printer Paper Installation/Replacement

1. Lift the printer access door and pull the printer head release lever forward to disengage the printer. Remove the paper spindle from the paper carriage.
2. Insert the paper spindle through a new roll of thermal paper. Use the proper thermal paper (Abbott LN 9684-07).
3. Insert the paper spindle into the two notches on the paper carriage with the thermal paper feeding from the back and underneath of bottom of the roll.

**CAUTION:** The thermal paper has a heat sensitive coating on one side. Results will not print if the thermal paper has been installed improperly on the paper carrier with the paper feeding from the top.

4. Thread the thermal paper through the thermal printer per the illustration below and align paper evenly between the paper guides.



5. Push the printer head release lever towards the back of the printer. The lever should now be in the vertical position.
6. Guide the thermal paper through the paper exit slot in the printer access door as the door is closed.

7. Advance the thermal paper one line at a time by pressing **PRINT**.
8. Press **TEST 5.4.1 RUN** to check the operation of the printer. Press **STOP** to return to [READY].

**CAUTION: Printed results on thermal paper have special requirements:**

- For long term storage, it is suggested that printouts be photocopied (print quality may be affected over a long period of time)
- Any type of adhesive tape placed over results may affect print quality
- Any aerosols, solvents, or petroleum products on or around thermal paper may affect print quality

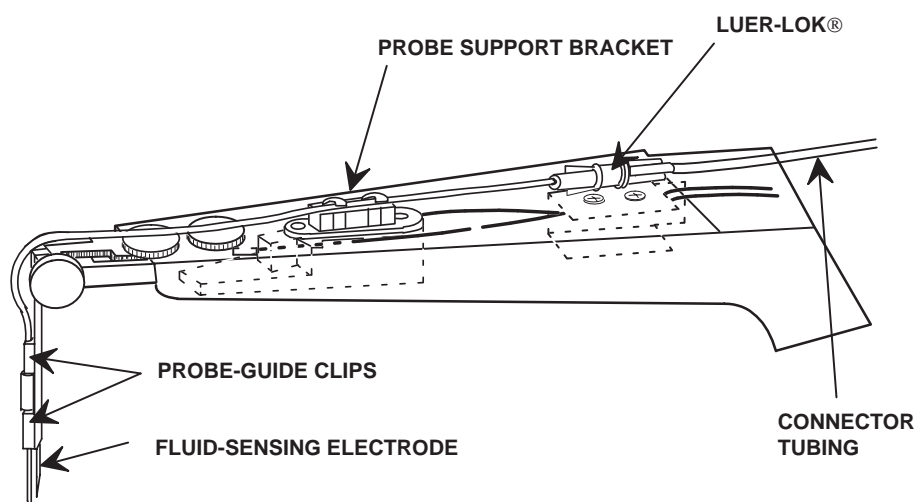
## Probe/Fluid-Sensing Electrode Replacement (LN 9967-02)

### Probe Replacement

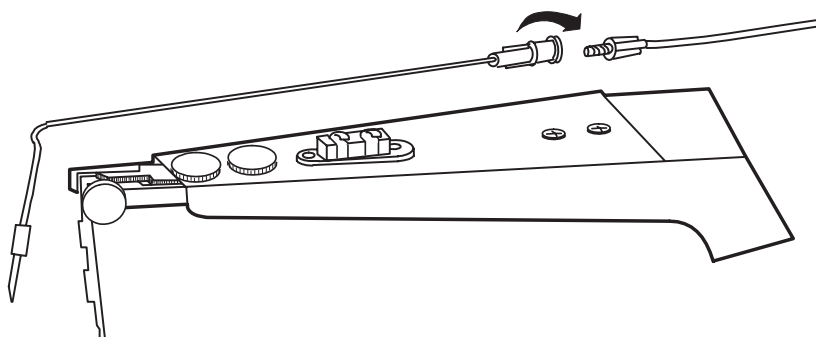
Before beginning this procedure, remove any carousels from the instrument, and move the boom arm to the center of the instrument by pulling on the boom-arm barcode reader assembly.

**DANGER:** The probe and the electrodes are sharp. To prevent injury, use caution in removing and replacing them.

1. Remove the stainless steel probe from the probe-guide clips on the front of the fluid-sensing electrodes.
2. Remove the probe from the probe support bracket by pushing the probe to the right.



3. Unscrew the LUER-LOK® connecting the probe to the connector tubing by turning counterclockwise.



4. To attach the new probe, screw the LUER-LOK® of the new probe into the connector tubing by turning clockwise.
5. Connect the probe to the fluid-sensing electrodes by snapping the probe guide into the probe-guide clips on the front of the electrodes.

6. Secure the probe by inserting it into the two clips on the probe support bracket.
7. Perform an **automated probe positioning and boom calibration (Test 3.10)**.
8. Perform a reagent carousel calibration (**Test 3.13**).
9. Perform a 4-Pot reagent pack boom calibration (**Test 3.7**), if applicable.
10. Perform the **unit dose probe-positioning procedure**, reference **Section 5.0 Periodic** under **Probe-Positioning Check** and **Adjustment Procedure** and a **unit dose boom calibration (Test 3.6)**, if applicable.
11. When a probe is replaced, recalibration of assays may be necessary. Check to ensure that controls are in range.

### Fluid-Sensing Electrode Replacement

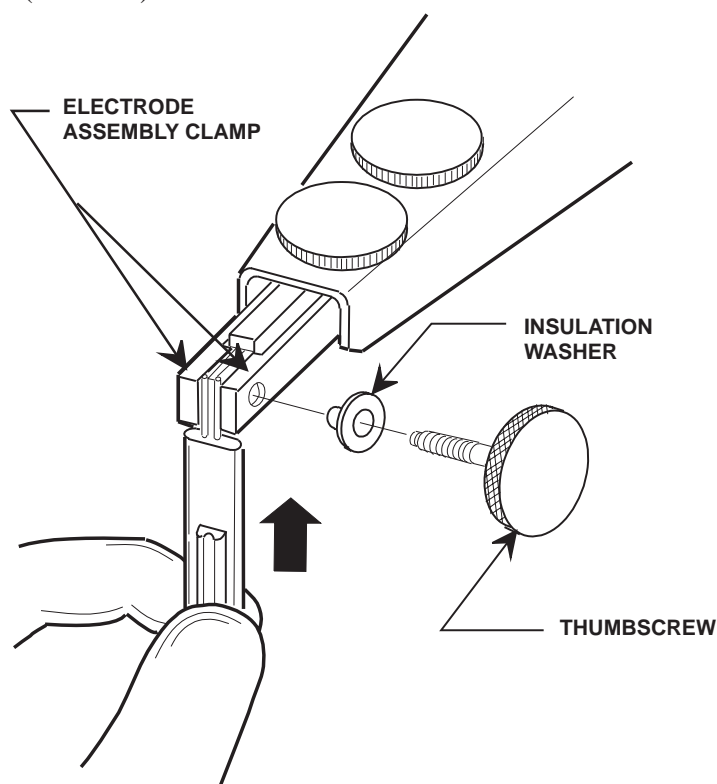
1. Remove the probe from the probe guide clips and support bracket according to the directions given under **Probe Replacement**.
2. Loosen the thumbscrew on the right side of the boom arm, and remove the electrodes.

**NOTE:** If the thumbscrew was removed, be sure that the washer is replaced. Failure to place the washer between the thumbscrew and the boom arm can cause an LLS FAIL error.

3. Insert the new electrodes, pointed end down, into the boom arm ensuring that the electrodes are pushed up into the boom arm as far as possible. **Do not force the electrodes into position.**

**DANGER:** The probe and the electrodes are sharp. To prevent injury, exercise care in removing and replacing them.

4. Tighten the thumbscrew on the right side of the boom arm until it is finger-tight.
5. Clip the probe into the detent of the fluid-sensing electrodes. Return the probe to its support bracket.
6. Perform an **automated probe positioning and boom calibration (Test 3.10)**.



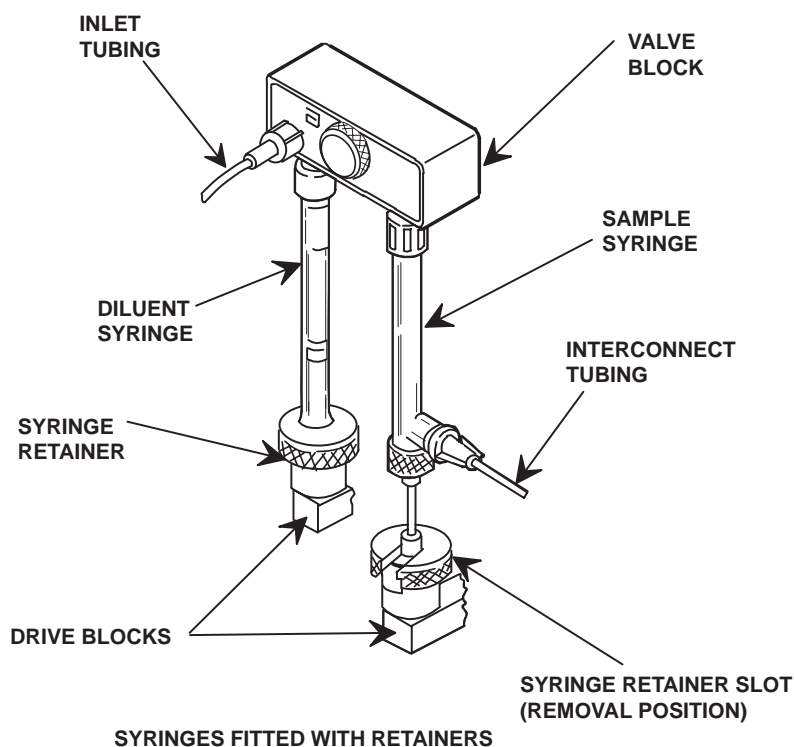
# Syringe Replacement

## Diluent Syringe (LN 9520-14)

## Sample Syringe (LN 9520-91)

1. Lift the buffer access door and remove the buffer container.
2. For removal of the **sample** syringe **only**, proceed to step 6.  
  
For removal of **both** syringes or **diluent** syringe **only**, continue to the next step.
3. Move the diluent syringe to the home (up) position:
  - a. Press **TEST 4.3 RUN** to activate dispenser assembly hand controls.
  - b. Place a test tube or other receptacle under the probe.  
**CAUTION: Placing a test tube under the probe is necessary to prevent buffer spills inside the instrument.**
  - c. Press **0** to home the syringe and to dispense buffer into the test tube.
  - d. Remove and discard the test tube with buffer.
4. Move the diluent-syringe drive block down approximately 1 inch:
  - a. Press **7** to change from step to tab increments.
  - b. Press **4** (10 times) to move the syringe down.
5. If the sample syringe does **not** require removal, press **STOP** and proceed to **step 7**.  
  
If the sample syringe must **also** be removed, move the sample-syringe drive block down approximately 1 inch:
  - a. Press **9** to activate control of the sample syringe.
  - b. Press **9** to change from step to tab increments.
  - c. Press **6** (10 times) to move the syringe down.
  - d. Press **STOP** to exit hand controls, and proceed to **step 7**.
6. Perform this step for removal of sample syringe only. Move the sample-syringe drive block down approximately 1 inch:  
  
The drive block may be manually pushed down, or moved down using the following hand-control procedure:
  - a. Press **TEST 4.3 RUN** to activate dispenser assembly hand controls.
  - b. Press **9** to activate control of the sample syringe.
  - c. Press **6** (10 times) to move the syringe down.
  - d. Press **STOP** to exit hand controls.

7. Loosen the syringe retainer(s) by turning it clockwise one to two revolutions. Align the slot in the syringe retainer outward, facing toward the front of the analyzer.
  8. Unscrew the syringe(s) from the valve housing. To remove a syringe:
    - a. Push down on the syringe barrel until the top of the syringe is free of the valve block.
    - b. Slip the syringe plunger out of the syringe retainer slot, and discard the syringe.
    - c. If not removing the sample syringe, proceed to **step 10**. If removing the sample syringe, continue to the next step.
  9. Remove the interconnect tubing:
    - a. Unscrew the interconnect tubing from the plastic fitting on the sample syringe.
    - b. If tubing is equipped with a plastic button, gently pull the plastic button off the left post of the liquid heater so that the interconnect tubing is exposed.
    - c. Remove the interconnect tubing from the left post.
    - d. Discard the tubing.
    - e. Attach the new interconnect tubing to the left post of the liquid heater.
- CAUTION: Ensure tubing is on securely to prevent leaks.**
- f. Gently push the button, if so equipped, on the left post to secure the tubing.





10. Slip the plunger of the new syringe(s) into the syringe retainer(s).
11. Pull up or push down on the syringe until you are able to screw the new syringe onto the valve housing. Ensure that the syringe is parallel to the back plate.
12. Ensure that the syringe plunger is seated in the detent on the top of the syringe drive block, then tighten the syringe retainer by turning the syringe retainer counter-clockwise.
13. **Replace the buffer container**, and press **PRIME** (five times) to remove bubbles.
14. Recalibration of assays may be necessary if either syringe is replaced. Check to be sure that controls are in range for each assay that is run.

## Tubing Replacement

### Probe-Connector Tubing (LN 9968-01)

1. Remove the probe from the probe guide clips and probe support bracket according to the directions in **Probe Replacement**. Do not remove the fluid-sensing electrodes.
2. If the tubing is equipped with a plastic button, gently pull the button off the right post of the liquid heater so that the probe connector tubing is exposed.
3. Remove the probe-connector tubing from the right post on the liquid heater. Unscrew the connector tubing from the probe assembly.
4. Attach the new connector tubing to the right post of the liquid heater.
5. Reinstall the probe, refer to the **Probe Replacement** section for instructions.
6. Prime the instrument to ensure that the tubing does not leak.

### Interconnect Tubing

1. Unscrew the interconnect tubing from the sample syringe.
2. If the tubing is equipped with a plastic button, gently pull the plastic button off the left post of the liquid heater so that the interconnect tubing is exposed.
3. Remove the interconnect tubing from the left post.
4. Discard the tubing.
5. Screw new interconnect tubing into the sample syringe.
6. Attach interconnect tubing to the left post of the liquid heater.

**CAUTION:** Ensure that the tubing is secure enough to prevent leaks.

7. Gently push the button, if so equipped, on the left post to secure the tubing.
8. Prime the instrument several times to ensure that the tubing does not leak, and the buffer is being dispensed from the probe.

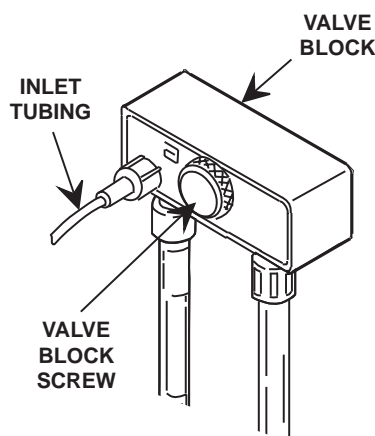
### Inlet Tubing

1. Unscrew the inlet tubing from the front of the valve block.
2. Allow the remaining buffer to drain into the buffer bottle. Remove the tubing from the buffer bottle and discard the used tubing.
3. Attach the new inlet tubing to the valve block.
4. Insert the end of the tubing into the buffer bottle.
5. Prime the instrument several times to ensure that the tubing does not leak and that the buffer is being dispensed out the probe.

**NOTE:** Ensure that the inlet tubing is not crimped when the buffer access door is closed.

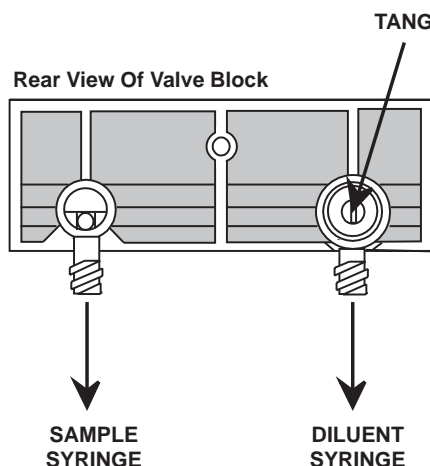
# Valve Block Replacement (LN 9520-15)

1. Unscrew the buffer inlet tubing from the front of the valve housing. Remove the buffer container.
2. Remove both the sample and diluent syringes. Refer to [Syringe Replacement procedure](#) in this section.
3. Unscrew and remove the valve block screw.



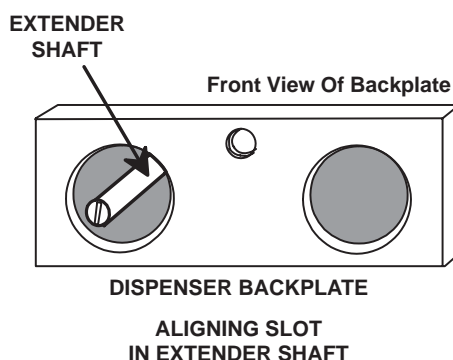
VALVE BLOCK HOUSING

4. Pull the valve block off and discard.
5. On the replacement valve, determine whether the tang on the inside of the right-hand valve is in a horizontal or vertical position.



VALVE BLOCK (REAR VIEW)

6. Determine whether the slot in the valve extender shaft (left-hand opening) on the dispenser backplate is horizontal or vertical.
7. If both the tang and the slot are in the same position, install the valve block with the syringe attachment connectors on the lower side. Tighten the valve block screw. Ensure that the valve tang completely engages into the valve extender shaft and there is no space on the top between the valve and the dispenser backplate.
8. If the tang and slot are not in the same position, use a blade screwdriver to turn the extender shaft so that the slot is in the same position as the tang. Install the valve with the syringe attachment connectors on the lower side. Tighten the valve block thumbscrew.



#### EXTENDER SHAFT ALIGNMENT

9. Reattach both the sample and diluent syringes.
10. Screw the inlet tubing into the front of the valve housing. Place the buffer container on the platform and insert the inlet tubing all the way into the container.
11. Prime the instrument several times to ensure that the buffer is being dispensed properly.

**NOTES:** If the buffer does not prime after replacing the valve, recheck the valve tang and the extender shaft positions. Also, ensure that the tube fittings are attached securely to avoid leaks.

If the buffer still does not prime, remove the valve block and rotate the extender shaft 180 degrees, then reinstall the valve and syringes and prime the instrument.

12. Recalibration of assays may be necessary when the valve block is replaced. Check to be sure that controls are in range for each assay that is run.

## Introduction

This section provides the information necessary to define, isolate, and resolve operational and component problems.

This information is presented in three categories:

1. **Displayed Error Codes** - Error codes that appear on the instrument's display.
2. **Printed Error Codes** - Error codes that are printed out during instrument operation.
3. **Observed Problems** - Problems that occur during operation.

The explanations of the error code or observed problem include a description of the possible causes and resolutions.

After following all corrective action procedures, if assistance is still required, contact the **Customer Support Center**.

Guidelines for using the troubleshooting guide:

- The final step for all troubleshooting actions, whether stated or not, is to contact the Customer Support Center if a problem cannot be resolved. The telephone number is (800) 527-1869 in the U.S.A.
- For corrective actions that require a system or diagnostic check, refer to **Section 4.0 - Diagnostic Checks**.
- For corrective actions requiring cleaning, adjusting, checking, or replacing components, refer to **Section 5.0 - Maintenance**.
- If corrective actions require power interruption of 30 minutes or longer, the TDxFLx<sup>®</sup> System should be allowed to warm up for 30 minutes after power is restored. Failure to do so may result in heater error messages.



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A C HTR BRK FAIL

Possible Cause	Corrective Action
Air heater continues to remain below specification for an extended period of time.	<div><div>1. Press <b>STOP</b>.</div><div>2. Call the <b>Customer Support Center</b> immediately.</div></div>

A C HTR SPC FAIL

Possible Cause	Corrective Action
Air heater continuously below specifications.	<div><div>1. Air heater will automatically shut off.</div><div>2. Press <b>STOP</b>. Allow system to return to [READY] before continuing with normal operation.</div><div>3. If heater continues to be out of specification, call the <b>Customer Support Center</b>.</div></div>

A H HTR BRK FAIL

Possible Cause	Corrective Action
Air heater continues to remain above specification for an extended period of time.	Call the <b>Customer Support Center</b> immediately.

A H HTR SPC FAIL

Possible Cause	Corrective Action
Air heater continuously above specifications.	<div><div>1. Air heater will automatically shut off.</div><div>2. Press <b>STOP</b>. Ensure at least 6" of space on all sides of the TDxFLx<sup>®</sup> Analyzer. Allow system to return to [READY] before continuing with normal operation.</div><div>3. Check to make sure nothing is blocking fan underneath the TDxFLx<sup>®</sup> Analyzer.</div><div>4. Check to be sure the air fan filter is clean. <b>Wash filter</b> as instructed in <b>Section 5.0 Maintenance</b> if necessary.</div><div>5. Check to be sure the air fan filter is properly seated.</div><div>6. If heater continues to be out of specification, call the <b>Customer Support Center</b>.</div></div> <div>For any procedure during which power to the TDxFLx<sup>®</sup> System is interrupted for 30 minutes or more, the instrument should be allowed to warm up for 30 minutes after power is restored to avoid heater error messages.</div>

A HTR FAILURE

Possible Cause	Corrective Action
Air heater not operational.	Call the <b>Customer Support Center</b> immediately.

AIR HTR T =

Possible Cause	Corrective Action
Temperature of air heater out of specification.	Momentarily displayed, repeat corrective action steps for air heaters SPC and BRK FAIL messages.

ALIQUOTING ERROR

Possible Cause	Corrective Action
During panel aliquoting, liquid splashed into a sample cartridge in a panel position other than the first.	<div><div>1. Replace the sample cartridge in error.</div><div>2. Pipette sample into the new sample cartridge.</div><div>3. Restart the run.</div></div>

ASSAYS DISAGREE

Possible Cause	Corrective Action
If a unit dose cartridge is read as a different assay than the first cartridge read, during unit dose calibration.	<div><div>1. When calibrating a unit dose assay, ensure all cartridges are for the same assay.</div><div>2. Replace the cartridge causing the error or use the <b>Barcode-Override option</b>.</div></div>

BAD # - RE-ENTER

Possible Cause	Corrective Action
Entering invalid assay numbers.	<div>1. Re-enter assay number ensuring that number is a valid assay number.</div>
Pressing STORE without entering valid assay numbers.	<div>2. Re-enter reagent pack barcode number, ensuring that the number is a valid 13-digit number.</div>
Entering illegal (less than 13 digits) reagent pack barcode label number.	

BARCODE FAIL

Batch/Unit Dose	
Possible Cause	Corrective Action
No reagent pack in instrument.	1. Press <b>STOP</b> .
Reagent pack, unit dose cartridge label, or carousel not seated properly.	2. Reseat reagent pack.
Reagent pack label, unit dose cartridge, or sample carousel label not clean.	3. Ensure that the <b>batch-pack adapter</b> is properly installed.
Boom-arm barcode reader dirty.	4. Check barcode reader or boom arm for obstruction and remove if found. Also check length of probe tubing.
Reagent pack vial insert not straight.	5. Clean label on reagent pack and carousel. (Use water dampened cotton swab.)
Label not seated properly.	6. Clean barcode reader. (Use water dampened cotton swab.)
Boom-arm barcode reader not properly aligned.	7. Straighten vial insert in reagent pack or use a new reagent pack.
Boom-arm barcode reader not sensing.	8. Use another carousel or reagent pack to see if problem still occurs.
Boom-arm barcode reader not seated in boom arm properly.	9. Disable door lock, pressing <b>SYSTEM 2.2 EDIT 0 STORE STOP</b> . Place reagent pack with vial caps removed and carousel into the instrument, leave access door open. Initiate a run and determine if error is occurring on carousel or reagent pack. Enable door lock, pressing <b>SYSTEM 2.2 EDIT 1 STORE STOP</b> .
Boom-arm barcode reader reads a unit dose carousel as a batch carousel, then tries to find a reagent pack barcode label.	10. Use <b>Test 4.4</b> to check reading performance ( <b>SYSTEM</b> for reagent pack, <b>PRIME</b> for carousel).
	11. Determine the white to black transition point on the sample carousel and edit <b>SYSTEM 3.12</b> and <b>3.13</b> as applicable.
	12. Use <b>Barcode-Override procedure</b> if unable to correct problem.
	13. If unable to correct the problem, call the <b>Customer Support Center</b> .
<b>System 3.10 Parameter - DAC</b> not properly set.	
<b>Batch-pack adapter</b> not seated properly.	

BARCODE FAIL (continued)

Random Access

Possible Cause	Corrective Action
Reagent carousel not detected when attempting a random access run. Instrument will go into batch mode of operation and will not detect batch reagent pack.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Ensure reagent carousel is properly seated on centerpost.</li><li>3. Clean reagent carousel sensor located at the 12 o'clock position.</li><li>4. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>
Reagent carousel home sensor not working properly.	

BOOM OUT OF SPEC

Possible Cause	Corrective Action
Z-boom step number not 172 or 173 for one or more positions, during <b>Automated Probe Positioning and Boom Calibration (Test 3.10)</b> .	Refer to <b>AUTO BOOM CAL OUT OF SPEC</b> under Printed Error Codes.

BUFFER EMPTY

Possible Cause	Corrective Action
Volume of buffer insufficient.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Remove any obstruction found under platform.</li><li>3. <b>Replace buffer bottle</b>.</li><li>4. Press <b>PRIME</b> three times.</li><li>5. If problem reoccurs with new buffer bottle, press <b>STOP</b>. Press <b>TEST 4.3 RUN 9</b>. Lift and reseal buffer twice to ensure buffer sensor resets.</li><li>6. If [B=Y] with buffer on the platform and [B=N] with no buffer on the platform, the buffer sensor is functioning, but the buffer platform needs adjusting.</li><li>7. Refer to <b>Section 5.0 Maintenance</b> for the Buffer Platform Adjustment procedure.</li><li>8. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>
Obstruction under buffer platform.	
Buffer platform bent.	
Buffer sensor failure.	

BUFFER PRESENT

Possible Cause	Corrective Action
Did not lift buffer bottle when running Test 5.7.	1. Repeat Test 5.7.
Buffer sensor failure.	2. Lift the buffer bottle when prompted to do so by the display.
	3. If unable to correct the problem, call the Customer Support Center.

CALIB. ABORTED

Possible Cause	Corrective Action
During calibration, an error was encountered for each replicate of a calibrator level, therefore no concentration can be determined for that calibrator. No further calibrators, controls or samples will be pipetted.	1. The error message(s) printed for the affected calibrator must first be addressed. See the appropriate section of this troubleshooting guide.
	2. Repeat the calibration run, repipetting all calibrators and controls (using clean, previously unused cartridges and cuvettes).
	3. If unable to correct the problem, call the Customer Support Center.

CAL REPS BAD

Possible Cause	Corrective Action
This message will appear when SYSTEM 4.2 is used to display calibration data and the criteria defined by assay parameter XX.6 is not met.	Refer to CAL REPS INCORRECT FOR CALIBRATION under Printed Error Codes.

CALVOL ILLEGAL

Possible Cause	Corrective Action
Calibration volume incorrect.	1. Edit calibration volume per the assay manual insert.
	2. If unable to correct the problem, call the Customer Support Center.

CAR LBL ERR-RUN?

Possible Cause	Corrective Action
Message displayed during Photo Calibration if a barcode read failure occurred or if the Fluorometric Standards Function Test Set Carousel is not in the TDxFLx <sup>®</sup> Analyzer.	<div><div>1. Press <b>STOP</b> if a valid X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel is not in the TDxFLx<sup>®</sup> Analyzer.</div><div>2. Press <b>RUN</b> if a valid X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel is in place.</div><div>3. Clean the barcode label on the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel and press <b>RUN</b>.</div><div>4. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

CAR POS ERROR

Possible Cause	Corrective Action
The location of the carousel does not match the correct position required to perform the run using Interactive Dilution Protocol.	<div><div>1. Wash and dry the probe.</div><div>2. Repeat run.</div><div>3. If message recurs, call the <b>Customer Support Center</b>.</div></div>
Liquid level sense error may have occurred during Interactive Dilution Protocol.	

CHECK WASTE CUP

Possible Cause	Corrective Action
Normal message after approximately 25 prime cycles have been completed if <b>System 2.11</b> is set to 1. Number of prime cycles will be approximately 174 if <b>System 2.11</b> is set to 2.	<div><div>1. Press <b>STOP</b>.</div><div>2. Empty waste cup and replace.</div><div>3. Continue operation.</div></div>



CHK ERR

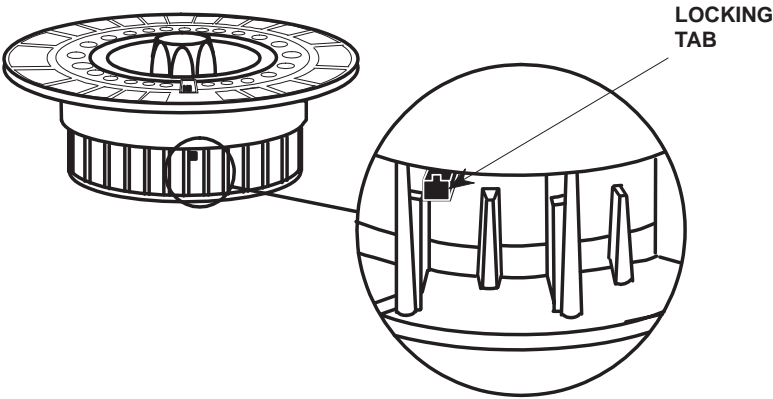
**NOTE:** This code displays on the reagent display.

Possible Cause	Corrective Action
Internal self-diagnostic test failure.	<div><div>1. Press <b>STOP</b>.</div><div>2. Call the <b>Customer Support Center</b>.</div></div>

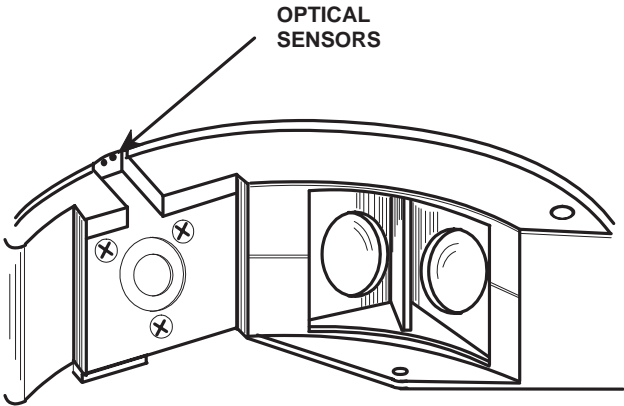
CLOSE THE DOOR

Possible Cause	Corrective Action
Access door left open after the initialization of a random access run.	<div>1. Close the access door.</div> <div>2. If troubleshooting with the access door open, you must set <b>System 2.2</b> to 0.</div>
Optical door sensor dirty.	<div>3. If the optical sensor has failed, disable the door lock using <b>SYSTEM 2.2 EDIT 0 STORE STOP</b>. Report failure to the <b>Customer Support Center</b>.</div>
Optical door sensor defective.	<div>4. If unable to correct the problem, call the <b>Customer Support Center</b>.</div>

Possible Cause	Corrective Action
Sample carousel not locked.	1. Press <b>STOP</b> and remove sample carousel.
Lock tab obstructed, dirty or worn.	2. Turn carousel handle lock clockwise and return the carousel to centerpost.
Sensor in optics assembly obstructed or dirty.	3. Remove any visible obstructions.
	4. Clean locking tab on carousel. If coating is worn, apply a coating of white liquid correction fluid.



5. Locate the optical sensors on the optics assembly. The optical sensor consists of two very small lenses and is located inside the indentation along the top edge of the optics assembly.



6. Dampen a cotton swab with deionized water and carefully clean the optical sensor on the optics assembly.
7. If unable to correct the problem, call the **Customer Support Center**.

CRSL STEP LOSS

Possible Cause	Corrective Action
There is an obstruction preventing sample carousel movement.	1. Press <b>STOP</b> .
Sample carousel not properly seated on centerpost.	2. Look for obstruction and remove. Reseat carousel on centerpost.
Sample carousel teeth have been damaged by dropping or melting.	3. Clean carousel gear.
	4. Check teeth underneath the carousel. If chipped, or otherwise damaged, replace the carousel. Clean the teeth if dried buffer is present.
	5. Clean the carousel sensor located at the 9 o'clock position of the baseplate with a forced air source. Refer to <b>Section 5.0 Maintenance</b> , for carousel home sensor cleaning.
	6. If unable to correct the problem, call the <b>Customer Support Center</b> .

CUV MISCOUNT

Possible Cause	Corrective Action
The number of cuvettes on the carousel does not match the correct number of cuvettes required to perform the run using Interactive Dilution Protocol.	1. Press <b>STOP</b> .
	2. Ensure that the appropriate number of cuvettes are loaded on the carousel.
	3. Continue operation.

CUV SENSOR ERR

Possible Cause	Corrective Action
Tried to run <b>Test 5.7</b> without X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel.	1. Press <b>STOP</b> .
Cuvette sensor obstructed or malfunctioning.	2. Call the <b>Customer Support Center</b> .

DATE \_\_ \_\_ . \_\_ \_\_ . \_\_ \_\_

Possible Cause	Corrective Action
Instrument power has just been turned on. (Can occur after a momentary interruption of power.)	<div><div>1. Enter the date. Each entry must be two-digits separated by pressing the “.” key. When the date is entered correctly press <b>STORE</b>.</div><div>2. Display shows [TIME __ __ . __ __ . __ __]</div><div>3. Enter time using military (24 hour) time. Each entry must be two-digits separated by pressing the “.” key. When the time is entered correctly press <b>STORE</b>.</div><div>4. Display shows [READY], press <b>PRIME</b>.</div><div>5. Begin operation as necessary.</div></div>
DEG C < 30.0	

Possible Cause	Corrective Action
Temperature entered during Temperature Calibration was less than 30.0°C.	<div><div>1. Press <b>CLEAR</b>.</div><div>2. Reenter correct temperature.</div><div>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>
DEG C > 37.0	

Possible Cause	Corrective Action
Temperature entered during Temperature Calibration was greater than 37.0°C.	<div><div>1. Press <b>CLEAR</b>.</div><div>2. Reenter correct temperature.</div><div>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>
DLNT JAMMED DLNT NOT HME DLNT STEP LOSS	

Possible Cause	Corrective Action
Long-term nonuse with salt buildup in dispenser components. Valve malfunctioning. Faulty diluent syringe seal. Dispenser failure.	<div><div>1. Press <b>STOP</b>.</div><div>2. Press <b>PRIME</b> three times.</div><div>3. Inspect <b>valve block</b> and <b>syringes</b> for damage or salt build-up and replace as necessary.</div><div>4. If not corrected, <b>replace diluent syringe</b>.</div><div>5. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

DONE-REMOVE RPAK

Possible Cause	Corrective Action
Normal message that occurs at the end of a random access or batch assay or calibration run. A beep will sound and the display returns to [READY].	<div><div>1. Open access door and remove reagent pack/carousel. Return pack to proper storage, per labeling.</div><div>2. Close access door.</div></div>

DOOR CLOSED

Possible Cause	Corrective Action
Access door not opened properly in <b>Test 5.7</b> . Optical sensor defective or misaligned.	<div><div>1. Open access door and repeat <b>Test 5.7</b>.</div><div>2. Ensure the access door is fully opened when you are prompted by the display to open it.</div><div>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

DOOR OPEN

Possible Cause	Corrective Action
Access door left open after the initialization of a random access run. Optical door sensor dirty. Optical door sensor defective.	<div><div>1. Close the access door.</div><div>2. If troubleshooting with the access door open, you must set <b>System 2.2</b> to 0.</div><div>3. If the optical sensor has failed, disable the door lock using <b>SYSTEM 2.2 EDIT 0 STORE STOP</b>. Report failure to the <b>Customer Support Center</b>.</div><div>4. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

DSP ERR

**NOTE:** This code displays on the reagent display.

Possible Cause	Corrective Action
Internal self-diagnostic test failure.	<div><div>1. Press <b>STOP</b>.</div><div>2. Call the <b>Customer Support Center</b> with details.</div></div>

DUPLICATE RPAK

Possible Cause	Corrective Action
Using two wedge reagent packs of same assay on the same run.	1. Press <b>STOP</b> .
Reagent barcode reader dirty.	2. Check reagent carousel for duplicate wedge reagent packs and remove if found.
Wedge barcode label damaged, dirty, or not seated properly.	3. Reseat reagent pack.
Wedge not seated properly on reagent carousel.	4. Check the reagent carousel assembly for obstructions and remove if found.
Reagent carousel not working properly.	5. Clean label on reagent pack and carousel. (Use water-dampened cotton swab.)
Reagent barcode reader not properly aligned.	6. Clean reagent barcode reader. (Use water-dampened cotton swab.)
	7. Perform <b>Reagent Carousel Calibration (Test 3.13)</b> .
	8. Use <b>Barcode-Override procedure</b> if you are unable to correct the problem.
	9. If unable to correct the problem, call the <b>Customer Support Center</b> .

DUP PAK

**NOTE:** This message appears on the reagent display.

Possible Cause	Corrective Action
Using two wedge reagent packs of same assay on the same run.	1. Press <b>STOP</b> .
Reagent barcode reader dirty.	2. Check reagent carousel for duplicate wedge reagent packs and remove if found.
Wedge barcode label damaged, dirty, or not seated properly.	3. Reseat reagent pack.
Wedge not seated properly on reagent carousel.	4. Check the reagent carousel assembly for obstructions and remove if found.
Reagent carousel not working properly.	5. Clean label on reagent pack and carousel. (Use water-dampened cotton swab.)
Reagent barcode reader not properly aligned.	6. Clean reagent barcode reader. (Use water-dampened cotton swab.)
	7. Perform <b>Reagent Carousel Calibration (Test 3.13)</b> .
	8. Use <b>Barcode-Override procedure</b> if you are unable to correct the problem.
	9. If unable to correct the problem, call the <b>Customer Support Center</b> .

Possible Cause	Corrective Action
This message will be displayed if any barcodes on a unit dose cartridge are not read properly during an assay run. Occurs after all cartridges have been read.	<div><div>1. Press <b>NEXT</b>. The following will be displayed:</div><div>LOC 1 ASSAY # _ _</div><div><p><b>NOTE:</b> The system will allow 15 seconds to begin to correct this error. If step 1 is not started within 15 seconds, the system will continue to the next position and the position causing the error will not be assayed.</p><div><div>2. DO NOT OPEN DOOR. Check the printout to determine which cartridge is causing the error. <b>BARCODE FAIL</b> will be printed in place of the assay name for the cartridge in error.</div><div>3. Continue to press <b>NEXT</b> until the location of the cartridge causing the error message is displayed.</div><div>4. Enter the correct assay number for that cartridge and press <b>STORE</b>.</div><div>5. Repeat steps 3 and 4 for any other positions in error.</div><div>6. Press <b>RUN</b> to resume reading. A corrected list of assays will be printed.</div><div>7. If the list is correct when [ASSAY LIST OK?] appears in the display, press <b>STORE</b> to start the assay run. If the list is incorrect, repeat Steps 3 and 4 above to enter the correct assay number.</div><div>8. If barcode failures occur often, align the barcode reader by performing a Unit Dose Boom Calibration (<b>Test 3.6</b>). Refer to <b>Section 5.0 Maintenance</b> for the procedure.</div><div>9. If unable to correct the problem, contact the <b>Customer Support Center</b>.</div></div></div></div>

Possible Cause	Corrective Action
Occurs when any cartridge after Position 1 cartridge is misread by the barcode reader during a unit dose calibration run.	<div><div>1. Verify that all unit dose cartridges loaded on the carousel are of the same assay.</div><div>2. If error recurs, press <b>NEXT</b>. The display reads:</div><div>ASSAY # _ _</div><div>3. Enter the correct assay number and press <b>RUN</b>. Calibration will begin.</div></div>

EXTRA CUVETTE(S)

Possible Cause	Corrective Action
When running in the random access mode, the number of cuvettes on the sample carousel does not correspond to the number of samples entered on the assay load list.	<div><div>1. Check carousel to ensure no used cuvettes remain from a previous run.</div><div>2. Check the assay load list to ensure that the number of tests entered corresponds to the number of tests on the carousel.</div><div>3. Repeat <b>Unit Dose Barcode Override procedure</b> ensuring that an assay number is entered for each position containing a unit dose cartridge.</div><div>4. Repeat the CRP calibration ensuring that no controls or unknowns are put on the carousel.</div></div>
When using the <b>Unit Dose Barcode Override procedure</b> , fewer positions are edited than are present on the carousel.	
When calibrating CRP, if controls or unknowns have been put on the carousel following the calibrators.	

F TO D FAIL

Possible Cause	Corrective Action
Frequency to digital failure during temperature monitoring.	Call the <b>Customer Support Center</b> with all information.

F-SET IN PROCESS

Possible Cause	Corrective Action
Factory set, <b>Test 6.2</b> is being performed.	<div>No corrective action. When software is upgraded, a factory set is required. System and assay parameters are set to their factory values. Assay calibration curves are not lost during this test.</div> <div><b>NOTE:</b> If the user wants to erase all assay calibration curves, this may be done by performing <b>Test 6.5</b> (Zero Calibration Curve), along with <b>Test 6.2</b>.</div> <div><b>CAUTION:</b> <b>Tests 6.2 and 6.5</b> are intended for Factory Testing and Service <b>ONLY</b>. Neither of these should be performed without first consulting the <b>Customer Support Center</b>. Otherwise, damage to the instrument could result.</div>



GAIN MISMATCH

Possible Cause	Corrective Action
Photo Check Gain (Test 2.2.1) did not match Photo Cal Gain (Test 3.4.1) when either test was run.	<div><div>1. Press <b>STOP</b>.</div><div>2. Edit Test 2.2.1. and Test 3.4.1, 3.4.2., and 3.4.4 parameters to match the values on the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label.</div></div>

ILLEGAL ASSAY

Possible Cause	Corrective Action
Attempting to run an assay with parameter .21 (MN TRACER) at 0.	<div><div>1. Press <b>STOP</b>.</div><div>2. Perform Pipet Check (Test 2.3) to set the MN TRACER parameter.</div><div>3. If unable to correct the problem, call the Customer Support Center.</div></div>

ILLEGAL MODE

Possible Cause	Corrective Action
Attempting to run an assay with an undefined mode number for parameter .18 (MODE).	<div><div>1. Press <b>STOP</b>.</div><div>2. Edit assay MODE with correct number, depending on the pipetting sequence required for the assay being run (see the Assay Parameters section in the assay manual insert for that assay).</div></div>
Attempting to reprint with <b>SYSTEM 4.1</b> when parameter .14 (CRV FIT) is 0 or 1.	

ILLEG UD LD-LIST

Possible Cause	Corrective Action
FLM unit dose cartridges are loaded on the same carousel with another unit dose assay.	1. Press <b>STOP</b> .
Ethosuximide unit dose cartridges are loaded on the same carousel with another unit dose assay.	2. Remove the carousel from the TDxFLx <sup>®</sup> Analyzer.
Barcode label is misread as either FLM or Ethosuximide.	3. Verify that either Ethosuximide or FLM unit dose cartridges are present on the carousel. If so, proceed to step 4. If Ethosuximide or FLM cartridges are not present, perform <b>Test 3.6 Unit Dose Boom Calibration</b> .
	4. Remove the FLM and/or Ethosuximide unit dose cartridge(s) from the carousel.
	5. Reload the carousel. Re-enter the carousel load list. FLM and Ethosuximide must be run as the only assay on the carousel and not in combination with each other or with any other unit dose assay.
	6. If unable to correct the problem, call the <b>Customer Support Center</b> .

INSUFFIC. RGT

Possible Cause	Corrective Action
Batch reagent pack empty or it has reached its maximum number of tests.	1. Press <b>STOP</b> .
Reagent volume in the pack is not enough to complete the number of cuvettes present in the sample carousel.	2. If reagent pack is empty, replace it with a new one and repeat the run.
During <b>barcode override</b> , 13-digit barcode number of a previously used/empty batch pack was entered.	3. Verify the number of tests left in the reagent pack and load the sample carousel with the corresponding number of cuvettes.
In random access mode, volume of wedge reagent pack is insufficient to complete calibration run with the number of cuvettes present on the sample carousel.	4. Ensure that the correct 13-digit barcode number is entered correctly during <b>barcode override</b> .
	5. If unable to correct the problem, call the <b>Customer Support Center</b> .

INSUFFIC SPL

Possible Cause	Corrective Action
Minimum sample volume not detected.	1. Make certain that at least the minimum sample volume is present. Refer to the assay manual insert for the minimum sample volume required.
No sample in sample well.	2. Wash and dry probe and perform Automated Probe Positioning and Boom Calibration (Test 3.10).
Probe positioning incorrect in sample well.	3. If unable to correct the problem, replace probe and perform an Automated Probe Positioning and Boom Calibration (Test 3.10).
	4. Perform a buffer run (Test 3.14 Buffer Run or Test 3.15 Batch Buffer Run) and observe probe positioning. If not correct, run an Automated Probe Positioning and Boom Calibration (Test 3.10) or edit the appropriate system parameter.
	5. Check carousel for a broken or warped rim using Liquid Level Sensing Adjustment procedure or Z-boom Calibration procedure.
	6. Remove the probe and flush the end of the boom arm with water. Thoroughly dry the spaces and reattach the probe.
	7. If unable to correct the problem, call the Customer Support Center.

INVAL CRVFIT #

Possible Cause	Corrective Action
Attempting to run a calibration curve with curve fit 0 or 1.	Do not attempt to edit curve fit to 0 or 1. Refer to the assay manual insert under the appropriate assay section for the correct curve fit.

## INVALID ASSAY

Possible Cause	Corrective Action
Attempting to run an assay or calibration before assay is activated.	1. Press <b>STOP</b> .
Barcode reader misread reagent pack label as assay that has not been activated.	2. Use <b>SYSTEM 5</b> to activate assay if the MN TR (X.21) in the assay parameters is a value of zero. Call the <b>Customer Support Center</b> for activation code if necessary.
Failure to run pipet check after factory set.	3. If the assay is activated, verify that the reagent pack name is being read correctly by the TDxFLx <sup>®</sup> analyzer by using <b>Test 4.4</b> . <b>SYSTEM</b> to read reagent pack label. If correct, press <b>STOP</b> and <b>RUN</b> .
	4. Perform a <b>pipet check (Test 2.3)</b> .
	5. Reseat reagent pack.
	6. Check barcode reader or boom arm for obstruction and remove if found. Also check length of probe tubing.
	7. Clean label on reagent pack and carousel with water-dampened cotton swab.
	8. Clean barcode reader with water-dampened cotton swab.
	9. Straighten vial insert in reagent pack or use a new reagent pack.
	10. Use another carousel or reagent pack to see if problem still occurs.
	11. Disable door lock, pressing <b>SYSTEM 2.2 EDIT 0 STORE STOP</b> . Place reagent pack with vial caps removed and the sample carousel into the instrument, leave access door open. Initiate a run and determine if error is occurring on carousel or reagent pack. Enable door lock, pressing <b>SYSTEM 2.2 EDIT 1 STORE STOP</b> .
	12. Use <b>Test 4.4</b> to check boom-arm barcode reading performance ( <b>SYSTEM</b> for reagent pack, <b>PRIME</b> for carousel).
	13. <b>Perform Boom Cal (Test 3.2)</b> .
	14. Determine the white to black transition point and edit <b>System 3.12</b> and <b>3.13</b> as applicable.
	15. Use <b>Barcode Override Procedure</b> if unable to correct problem.
	16. If unable to correct the problem, call the <b>Customer Support Center</b> .

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**INVALID BARCODE**

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Possible Cause	Corrective Action
Barcode label cannot be decrypted due to entering invalid 13-digit barcode number during <b>barcode override</b> .	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. If using <b>barcode override</b>, ensure that 13-digit number is the same as that of the barcode label.</li><li>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>

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**INVALID CODE**

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Possible Cause	Corrective Action
Attempting to enter an incorrect code during edit function.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Proceed with editing assuring correct code is used.</li></ol>
Attempting to enter an incorrect code during activation of assay number.	

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**INVALID DATE**

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Possible Cause	Corrective Action
Invalid date was entered on power up.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Press <b>SYSTEM 1.1 EDIT</b>. Enter valid date.</li><li>3. Press <b>STORE, STOP</b>.</li></ol>

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**INVALID GAIN**

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Possible Cause	Corrective Action
Attempting to run <b>Photo Calibration or Photo Check</b> with improper gain.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Edit <b>Test 3.4.1</b> to gain indicated on X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label.</li><li>3. If running Photo Check, press <b>STOP</b> and edit <b>Test 2.2.1</b> to match labeled value on X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel.</li></ol>

KEEP DOOR CLOSED

Possible Cause	Corrective Action
<p>This reminder occurs if the access door is open for 6 minutes or more.</p> <p>If troubleshooting is to continue, close access door for 10 seconds before reopening.</p>	<ol style="list-style-type: none"><li>1. Close the access door.</li><li>2. If access door is closed and error message remains, edit <b>SYSTEM 2.2</b> to 0 (off) and report failure to the <b>Customer Support Center</b>.</li></ol> <p>For any procedure during which power to the TDxFLx<sup>®</sup> System is interrupted for 30 minutes or more, the instrument should be allowed to warm up for 30 minutes after power is restored to avoid heater error messages.</p>

LAMP OUT

**CAUTION:** Lamp and lamp housing can be very hot. Allow to cool before touching.

Possible Cause	Corrective Action
<p>Burned out lamp.</p> <p>Lamp not seated properly in housing.</p> <p>Aperture on left-hand wall of source lamp housing dirty.</p> <p>Contacts on lamp are dirty or connection loose.</p>	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>. <b>Replace lamp</b>. Refer to <b>Section 5.0 Maintenance</b>.</li><li>2. Check lamp operation by pressing <b>TEST 4.2 RUN PRIME</b>. If lamp turns on, press <b>STOP</b>. Ensure that the lamp is properly seated in the lamp housing. (The lamp ejector bar is to the left and the face of the lamp is parallel to the lamp housing wall.)</li><li>3. Clean aperture on left-hand wall inside source lamp housing with a cotton swab.</li><li>4. If problem still occurs, remove lamp and unplug from socket. Clean contacts with emery paper and reseat lamp securely into lamp socket and lamp housing.</li><li>5. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>

L C HTR BRK FAIL

Possible Cause	Corrective Action
<p>Liquid heater continues to remain below specification for an extended period of time.</p>	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Call the <b>Customer Support Center</b> immediately.</li></ol>

L C HTR SPC FAIL

Possible Cause	Corrective Action
Liquid heater continuously below specifications.	<div><div>1. Liquid heater will automatically shut off.</div><div>2. Press <b>STOP</b>. Allow system to return to [READY] before continuing with normal operation.</div><div>3. Press <b>PRIME</b> three times.</div><div>4. If heater continues to be out of specification, call the <b>Customer Support Center</b>.</div></div>

L H HTR BRK FAIL

Possible Cause	Corrective Action
Liquid heater continues to remain above specifications for an extended period of time.	<div><div>1. Press <b>STOP</b>.</div><div>2. Call the <b>Customer Support Center</b> immediately.</div></div>

L H HTR SPC FAIL

Possible Cause	Corrective Action
Liquid heater continuously below specifications.	<div><div>1. Liquid heater will automatically shut off.</div><div>2. Press <b>STOP</b>. Allow system to return to [READY] before continuing with normal operation.</div><div>3. If heater continues to be out of specification, call the <b>Customer Support Center</b>.</div></div>

LIQ HTR T =

Possible Cause	Corrective Action
Temperature of liquid heater out of specification.	Momentarily displayed, press <b>PRIME</b> several times.

LIQ SENSE ERROR

Possible Cause	Corrective Action
	Refer to <b>LIQ SENSE ERROR</b> under Printed Error Codes.

LIQ XTAL FAIL

Possible Cause	Corrective Action
Failure of liquid crystal polarizer.	<div><div>1. Press <b>STOP</b>.</div><div>2. Rerun <b>Photo Check (Test 2.2)</b>.</div><div>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

LIQUID LEVEL HI

Possible Cause	Corrective Action
	Refer to <b>LIQUID LEVEL HI</b> under Printed Error Codes.



Possible Cause	Corrective Action
Liquid on probe is creating a liquid bridge between two electrodes.	1. Press <b>STOP</b> .
Probe tip damaged or mispositioned.	2. Wash and dry probe.
Buffer salt bridge has formed between two electrodes.	3. Check cuvettes to be sure they were empty when the run started.
Splashing in predilution chamber.	4. Push tube all the way into buffer.
Used cuvettes not removed from carousel.	5. Press <b>PRIME</b> three times, checking for air bubbles. Refer to procedure for air bubble removal under <b>Observed Problems</b> .
Inlet tube not seated all the way into buffer.	6. Remove and reseal the probe; be sure thumbscrew on the right side of the boom arm is secure but not overtight. Ensure that there is an insulating washer between the thumbscrew and the boom arm.
Undetected empty buffer bottle.	7. <b>Check probe position</b> . Observe a <b>buffer run</b> . <b>Adjust as needed</b> .
Probe thumbscrew not properly secured.	8. <b>Use Test 4.4</b> to check the fluid sensing function of the probe and boom arm.
Thumbscrew washer missing.	9. Remove probe and flush boom-arm connection with deionized water. Thoroughly dry the boom and reattach the probe.
Liquid-level-sensing electrodes not properly inserted into end of boom arm.	10. <b>Clean the waste/wash station</b> as instructed in <b>Section 5.0 Maintenance</b> .
End of boom arm dirty from dried buffer salts.	11. If not corrected, <b>replace probe</b> .
If displaying data using <b>SYSTEM 4.2</b> , refer to <b>LLS FAIL</b> under Printed Error Codes.	12. Perform <b>Test 3.10 Automated Probe Positioning and Boom Calibration</b> .
<b>During Dispense Check (Test 6.3 )</b> if liquid in all of the pots (reagent, sample, and predilute) is not sufficient.	13. If unable to correct the problem, call the <b>Customer Support Center</b> .
Splashing in the waste/wash station due to improper alignment.	

## &gt; MX BKG

**Possible Cause**

Occurs when **SYSTEM 4.2** is used to recall assay data for an abused drug assay and the BLK I is greater than assay parameter XX.20 (MX BKG).

Occurs when **SYSTEM 4.2** is used to recall data for an abused drug assay and assay parameter XX.3 (BKG FAC) is set to 0.

**Corrective Action**

Refer to > **MX BKG** under Printed Error Codes.

## NET I LARGE

**Possible Cause**

This message will appear when **SYSTEM 4.2** is used to recall calibration data and the criteria defined by assay parameter .21 (MN TR) is not met.

**Corrective Action**

Refer to **NET I LARGE** under Printed Error Codes.

## NET I SMALL

**Possible Cause**

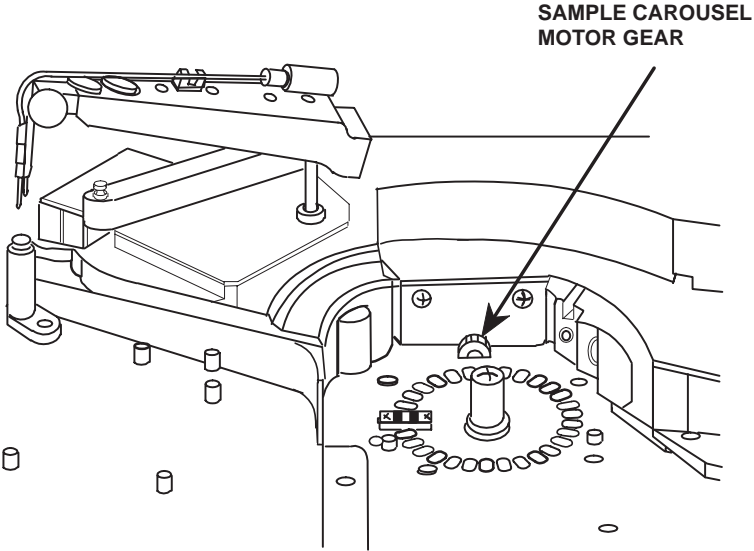
This message will appear when **SYSTEM 4.2** is used to recall calibration data and the criteria defined by assay parameter .21 (MN TR) is not met.

**Corrective Action**

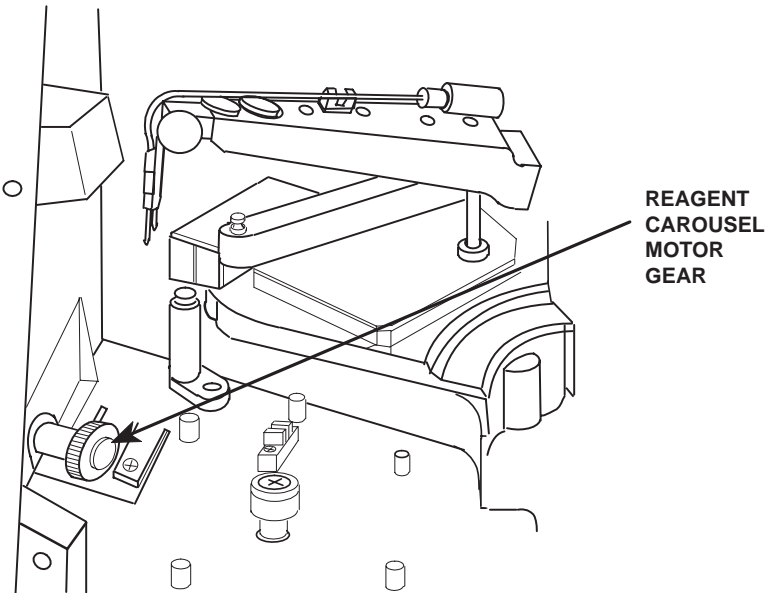
Refer to **NET I TOO SMALL** under Printed Error Codes.

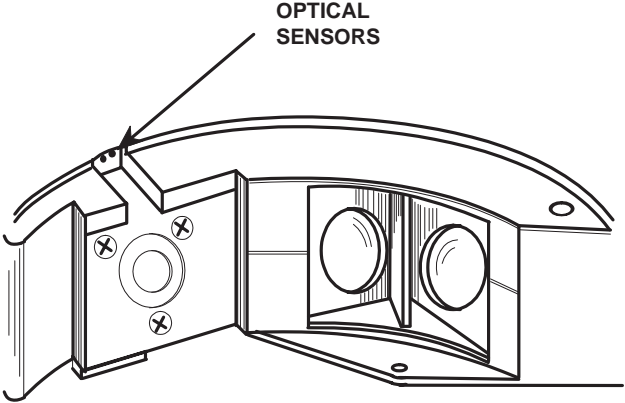
**NOTE:** The type of run determines which carousel may be the problem.

Possible Cause	Corrective Action
<b>Sample Carousel</b>	
No sample carousel in TDxFLx <sup>®</sup> Analyzer.	1. Press <b>STOP</b> .
Carousel not properly seated on centerpost.	2. Insert or reseal carousel on centerpost.
Carousel home optical sensor obstructed/dirty.	3. Look for and remove any obstruction near the optical sensor which is located at the 9 o'clock position on the base of the TDxFLx <sup>®</sup> Analyzer. Clean sensor, if needed, with forced air.
Carousel home tab broken.	4. Insert a different carousel.
Gear loose or obstruction on carousel stepper motor.	5. Locate the sample carousel motor gear. Turn the gear by hand and examine all gear teeth. Remove dirt or foreign objects.



6. If unable to correct the problem, call the **Customer Support Center**.

Possible Cause	Corrective Action
<b>Reagent Carousel</b> During <b>barcode override</b> , no reagent carousel in the TDxFLx <sup>®</sup> Analyzer. Reagent carousel not properly seated on centerpost. Reagent carousel home sensor obstructed/dirty. Reagent carousel motor gear loose, dirty, or damaged. No reagent carousel present during <b>Reagent Carousel Calibration (Test 3.13)</b> .	<ol style="list-style-type: none"> <li>1. Press <b>STOP</b>.</li> <li>2. Insert or reseal the reagent carousel on the centerpost.</li> <li>3. Look for and remove any obstruction near the optical sensor which is located at the 12 o'clock position on the reagent carousel platform.</li> <li>4. Insert a different reagent carousel.</li> <li>5. Locate the reagent carousel motor gear on the reagent carousel platform. Turn the gear by hand and examine all gear teeth. Remove dirt or foreign objects.</li> </ol>  <ol style="list-style-type: none"> <li>6. If unable to correct the problem, call the <b>Customer Support Center</b>.</li> </ol>

Possible Cause	Corrective Action
<p>Cuvette missing in carousel position (1-20) indicated.</p> <p>Carousel dirty.</p> <p>Cuvette sensor obstructed.</p> <p>When running in the random access mode, the number of samples entered in the sample loadlist does not correspond to the number of cuvettes on the sample carousel.</p>	<div><div><div><div><div>1. Press <b>STOP</b>.</div><div>2. Place cuvette into appropriate position.</div><div>3. Remove any obstruction near the optical sensor. Clean the optical sensors on the optics assembly with a cotton swab. (The optical sensor is located inside the indentation along the top edge of the optics assembly.)</div></div></div><div></div><div><div>4. Wash carousel.</div><div>5. If running a <b>Temperature Calibration (Test 3.1)</b>, a cuvette must be in Positions 9, 10, and 11.</div><div>6. Verify the sample loadlist to ensure that the number of tests entered corresponds to the number of cuvettes in the sample carousel.</div><div>7. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div></div></div> <div data-bbox="20 1895 1267 1930" data-label="Page-Footer"><div>45122-105</div><div>6-33</div><div>TDxFLx<sup>®</sup> System Operations Manual</div></div>

NO DATA AVAIL

Possible Cause	Corrective Action
After certain diagnostic and system tests, the assay or calibration data stored from the last run will not be allowed to reprint or be redisplayed.	If reprint or redisplay of data is required do not initiate these tests or another assay run until reprint or redisplay is completed.
During assay run, error occurred in all positions before any readings had taken place. No results available to reprint or display.	<div><div>SYSTEM 5</div><div>–</div><div>Activate Assay</div></div> <div><div>SYSTEM 6.2</div><div>–</div><div>Assay Categories</div></div> <div><div>Test 1.2</div><div>–</div><div>Life Test</div></div> <div><div>Test 2.1</div><div>–</div><div>Temp Check</div></div> <div><div>Test 2.2</div><div>–</div><div>Photo Check</div></div> <div><div>Test 3.1</div><div>–</div><div>Temperature Calibration</div></div> <div><div>Test 3.2</div><div>–</div><div>Boom Calibration</div></div> <div><div>Test 3.4</div><div>–</div><div>Photo Calibration</div></div> <div><div>Test 3.8</div><div>–</div><div>Turbo Carousel Calibration</div></div> <div><div>Test 3.10</div><div>–</div><div>Automated Probe Positioning and Boom Calibration</div></div> <div><div>Test 5.2</div><div>–</div><div>CPU Board Check</div></div> <div><div>Test 5.3</div><div>–</div><div>Memory Board Check</div></div> <div><div>Test 5.4</div><div>–</div><div>Printer and Driver Check</div></div> <div><div>Test 5.5</div><div>–</div><div>Input/Output Board Check</div></div> <div><div>Test 5.6</div><div>–</div><div>Front Panel Check</div></div> <div><div>Test 6</div><div>–</div><div>Special Tests</div></div>

NO SPLS PIPETTED

Possible Cause	Corrective Action
No samples in sample cartridges.	1. Press <b>STOP</b> .
Too little sample in sample cartridges to be detected.	2. Remove carousel and check sample wells.
R-boom not properly positioned.	3. Add proper amount of sample to sample cartridge.
Z-boom not properly positioned.	4. Ensure probe is properly installed in the boom arm and the thumbscrew is secure.
No sample detected in predilution well.	5. Check all connections in the dispenser assembly, especially tubing on liquid heater block.
	6. Observe probe position in predilution well and sample well by performing a <b>buffer run</b> .
	7. If problem persists, run <b>Automated Probe Positioning and Boom Calibration, Test 3.10</b> , and ensure the probe is centered in the sample and predilution wells.
	8. If problem persists, run <b>Test 3.5 (Section 4.0)</b> to <b>recalibrate Z-boom home</b> .
	9. <b>Check front to back probe positioning</b> in predilution well.
	10. If unable to correct the problem, call the <b>Customer Support Center</b> .

NO TRANSITION PT

Possible Cause	Corrective Action
Sample carousel barcode label not detected during Boom Calibration (Test 3.2 or Test 3.10).	1. Press <b>STOP</b> .
Barcode label not detected during Unit Dose Boom Calibration (Test 3.6).	2. Ensure a calibration carousel is being used in the Boom Calibration procedure.
Using assay carousel instead of calibration carousel during Boom Calibration (Test 3.2 or Test 3.10).	3. Check label on carousel for proper positioning.
Calibration carousel label not positioned properly.	4. Check sample carousel label to be sure it is clean and flat. Press down firmly across the label.
Sample carousel barcode labels dirty.	5. Clean boom-arm barcode reader with a water-dampened cotton swab.
Boom-arm barcode reader dirty.	6. Repeat Boom Calibration while watching operation. If unable to correct the problem, refer to “Boom Calibration Will Not Work Properly” in Observed Problems section.
Boom-arm barcode reader not positioned properly.	7. If carousel fails, use a new CAL carousel to run Boom Calibration. If necessary, press <b>TEST 3.2 PRINT</b> and edit the value in Test 3.2.5 to 260 and the value in Test 3.2.6 to 1661.
	8. If CONTINUE? appears in the display after several seconds when running Test 3.6 and 3.7, press <b>STORE</b> to continue, otherwise, press <b>STOP</b> .
	9. If unable to correct the problem, call the Customer Support Center.

NOT A PROGRAM

Possible Cause	Corrective Action
RUN pressed during displaying or editing of system, assay, or test parameters.	1. Press <b>STOP</b> .
	2. Complete editing of parameters.
	3. When display shows [READY] proceed with run.
	4. If unable to correct the problem, call the Customer Support Center.

NOT ENOUGH ROOM

Possible Cause	Corrective Action
The panel sample loadlist exceeds 20 positions.	Re-enter the sample loadlist using a mix of panels that does not exceed 20 positions.

NOT PROGRAMMED

Possible Cause	Corrective Action
A panel has been selected which has not been programmed.	<div><div>1. Print a Panel Report by pressing <b>TEST 6.9 RUN</b>. Verify that the panel has been programmed and enter the correct location.</div><div>2. Program the panel if it was not programmed.</div></div>

NOVRAM ERROR

Possible Cause	Corrective Action
NOVRAM will not accept calibration data.	See <b>NOVRAM ERRORS</b> under <b>Observed Problems</b> for possible causes.

NO WASTE CUP

Possible Cause	Corrective Action
Waste container missing.	1. Press <b>STOP</b> .
Waste container not properly installed.	2. Ensure waste container is present and properly installed.
Optical waste container sensor dirty.	3. Clean the optical sensor. Call the <b>Customer Support Center</b> for instructions.
Optical waste container sensor defective.	4. If optical sensor is defective, disable sensor by pressing <b>SYSTEM 2.11 EDIT 0 STORE STOP</b> (CUP SIZ = 0). Notify the <b>Customer Support Center</b> of failure.
	5. If unable to correct the problem, call the <b>Customer Support Center</b> .

O C HTR BRK FAIL

Possible Cause	Corrective Action
Optical heater continues to remain below specification for an extended period of time.	<div><div>1. Press <b>STOP</b>.</div><div>2. Call the <b>Customer Support Center</b> immediately.</div></div> <div>For any procedure during which power to the TDxFLx<sup>®</sup> System is interrupted for 30 minutes or more, the instrument should be allowed to warm up for 30 minutes after power is restored to avoid heater error messages.</div>



O C HTR SPC FAIL

Possible Cause	Corrective Action
Optical heater continuously below specifications.	<div><div>1. Optical heater will automatically shut off.</div><div>2. Press <b>STOP</b>. Allow system to return to [READY] before continuing with normal operation.</div><div>3. If heater continues to be out of specification, call the <b>Customer Support Center</b>.</div></div>

O H HTR BRK FAIL

Possible Cause	Corrective Action
Optical heater continues to remain above specifications for an extended period of time.	<div><div>1. Press <b>STOP</b>.</div><div>2. Call the <b>Customer Support Center</b> immediately.</div></div>

O H HTR SPC FAIL

Possible Cause	Corrective Action
Optical heater continuously above specifications.	<div><div>1. Optical heater will automatically shut off.</div><div>2. Press <b>STOP</b>. Allow system to return to [READY] before continuing normal operation.</div><div>3. If heater continues to be out of specification, call the <b>Customer Support Center</b>.</div></div>

OPT HTR T =

Possible Cause	Corrective Action
Temperature of optical heater when out of specification.	Momentarily displayed, follow the corrective action steps for <b>O H HTR SPC FAIL</b> .

OVERFLOW

Possible Cause	Corrective Action
Attempting to store too large a number during EDIT.	<div><div>1. Press <b>STOP</b>.</div><div>2. Edit parameter correctly.</div><div>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

PAK LBL READ ERR

Possible Cause	Corrective Action
No reagent pack in instrument.	<div>1. Press <b>STOP</b>.</div>
Reagent pack not seated properly.	<div>2. Ensure reagent pack is present and properly seated.</div>
Label not clean on reagent pack.	<div>3. Remove reagent pack. Wipe label to remove any dirt. Press finger along label to remove any air bubbles. Proceed with run.</div>
Bubble under label on reagent pack.	<div>4. Straighten vial insert in reagent pack or use a new reagent pack.</div>
Reagent pack vial insert crooked.	<div>5. Clean barcode reader with a damp cotton swab.</div>
Barcode reader dirty.	<div>6. Use another reagent pack to see if problem still occurs.</div>
Barcode reader not positioned properly over reagent pack label.	<div>7. Perform DAC Optimization procedure. Refer to <b>Section 5.0 Maintenance</b>.</div>
Barcode reader in boom arm not at proper height.	<div>8. Use <b>Barcode Override procedure</b> if unable to correct problem.</div>
Barcode reader not sensing.	<div>9. If problem occurs with all reagent packs, call the <b>Customer Support Center</b>.</div>

PAPER OUT

Impact Printer

Possible Cause	Corrective Action
Insufficient paper in printer.	1. Press <b>STOP</b> .
Paper not installed correctly.	2. Install new roll of printer paper.
Wires pulled off paper sensor connector.	3. Press <b>RUN</b> .
Paper sensor failure.	4. Reseat wires onto paper sensor connectors.
	5. Remove paper roll and tape paper sensor contact. If problem is corrected, gently bend metal plate (with paper sensor) toward center of printer. Remove tape. Reinstall paper roll.
	6. If unable to correct the problem, call the <b>Customer Support Center</b> .

Thermal Printer

Possible Cause	Corrective Action
Printer out of paper.	1. Press <b>STOP</b> .
Printer head release lever not engaged.	2. Ensure that the printer head release lever is pushed towards the back of the printer (engaged/vertical position).
Paper not installed correctly.	3. Install a new roll of thermal paper Abbott LN 9684-07.
Printer is broken.	4. Ensure that the thermal paper is properly installed.
	5. If unable to correct the problem, call the <b>Customer Support Center</b> .

PO TOO SMALL

Possible Cause	Corrective Action
This message will appear when <b>System 4.2</b> is used to display calibration data and the criteria defined by assay parameter .16 (MN POLA) is not met.	Refer to <b>PO TOO SMALL</b> under Printed Error Codes.

PREDIL LEVEL HI

Possible Cause	Corrective Action
	Refer to <b>PREDIL LEVEL HI</b> under Printed Error Codes.

PREDIL LEVEL LO

Possible Cause	Corrective Action
	Refer to <b>PREDIL LEVEL LO</b> under Printed Error Codes.

PUNC INCOMPLETE

Possible Cause	Corrective Action
Occurs when the software determines the probe cannot drop the <b>System 8.8</b> specified number of steps after first detecting foil without first getting to the liquid level low limit specified by <b>System 8.10</b> .	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Check that the cartridge is intact and in no way damaged.</li><li>3. <b>Check the position of the probe and correct as necessary.</b></li><li>4. Perform a <b>Z-boom Calibration</b>.</li><li>5. <b>Replace fluid-sensing electrodes</b> if necessary.</li><li>6. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>

RAM ERR

**NOTE:** This code displays on the reagent display.

Possible Cause	Corrective Action
Internal self-diagnostic test failure.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Call the <b>Customer Support Center</b> with details.</li></ol>

RBM JMD HME  
RBM NOT HME  
RBM STEP LOSS

Possible Cause	Corrective Action
Possible obstruction preventing boom arm from moving horizontally.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Look for obstruction and remove.</li><li>3. Check for sufficient length of probe tubing. If too short, <b>replace probe tubing</b>.</li><li>4. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>

REAGENT LEVEL LO

Possible Cause	Corrective Action
	Refer to <b>REAGENT LEVEL LO</b> under Printed Error Codes.

REAGENTS MISSING

Possible Cause	Corrective Action
A panel has been selected which includes a wedge reagent pack that has not been loaded onto the reagent carousel.	Load the missing wedge reagent pack onto the reagent carousel.

REMOVE CAROUSEL

Possible Cause	Corrective Action
Carousel has been left in TDxFLx <sup>®</sup> Analyzer for more than 5 minutes after a completed test run.	<div><div>1. Remove the carousel.</div><div>2. If problem persists after removing the carousel, call the <b>Customer Support Center</b>.</div></div>

READY      S=XX%

Possible Cause	Corrective Action
Instrument storing data in memory module.	See <b>DISPLAY SHOWS “READY S=XX%”</b> under Observed Problems section for possible causes.

RGNT LOAD ERROR

Possible Cause	Corrective Action
Loading two or more wedge reagent packs for a calibration run.	1. Press <b>STOP</b> .
Sample carousel barcode label misread as a calibration label.	2. Remove reagent carousel from instrument and check for multiple wedge reagent packs. Only the reagent for the assay to be calibrated is allowed on the carousel during a calibration run.
Using a calibration carousel for an assay run.	3. Clean sample carousel barcode label if dirty. Replace if damaged.
Initiating calibration run instead of assay run via <b>barcode override</b> .	4. Ensure use of an assay carousel and not a calibration carousel if a calibration is not being run.
	5. If unable to correct the problem, call the <b>Customer Support Center</b> .

RGNT TOO FULL

Possible Cause	Corrective Action
Vial not seated fully down into pack.	1. Press <b>STOP</b> .
Liquid film or air bubbles in vial opening.	2. Remove reagent pack from instrument.
Reagent pack not seated properly.	3. Break liquid film over vial opening.
Probe wet.	4. Push vial down into reagent pack. Replace reagent pack into instrument.
Probe not properly seated in end of boom arm.	5. <b>Check for proper installation of the batch-pack adapter</b> .
Probe thumbscrew loose.	6. Clean and dry probe.
Boom arm connectors dirty.	7. Press <b>PRIME</b> three times.
Z-boom not properly positioned.	8. Check that the probe is secured to the boom arm.
<b>Batch-pack adapter</b> not properly seated.	9. Remove probe and flush end of boom arm with water. Thoroughly dry with a tissue.
	10. Perform <b>Z-boom Calibration procedure (Test 3.5)</b> .
	11. If problem occurs with all reagent packs and no liquid has been added, <b>replace the probe</b> .
	12. If unable to correct the problem, call the <b>Customer Support Center</b> .

RGTCRSL STP LOSS

Possible Cause	Corrective Action
There is an obstruction preventing reagent carousel movement.	1. Press <b>STOP</b> .
Carousel not properly seated on centerpost.	2. Look for obstruction and remove. Reseat carousel on centerpost.
Carousel teeth have been damaged by dropping or melting.	3. Check and clean reagent carousel motor gear.
Loose or dirty motor gear.	4. Check teeth underneath the carousel. If chipped, or otherwise damaged, replace the carousel. Clean the teeth if dried buffer is present.
	5. Clean the carousel sensor located at the 12 o'clock position from the reagent carousel centerpost.
	6. If unable to correct the problem, call the <b>Customer Support Center</b> .

RGT DATABAS INIT

Possible Cause	Corrective Action
Failure in NOV RAM memory, where data information about reagents is stored, has caused all data to be lost.	1. Press <b>STOP</b> .
Database will be initialized and reset for future storage.	2. Call the <b>Customer Support Center</b> .

RNG TOO LARGE

Possible Cause	Corrective Action
This message will appear when <b>System 4.2</b> is used to redisplay calibration data and the criteria defined by assay parameter .15 (MX DEV) is not met.	Refer to <b>RANGE TOO LARGE</b> under Printed Error Codes.

SPAN TOO SMALL	
Possible Cause	Corrective Action
This message will appear when <b>System 4.2</b> is used to recall calibration data and the criteria defined by assay parameter .17 (MN SPAN) is not met.	Refer to <b>SPAN LESS THAN MIN SPAN</b> under Printed Error Codes.

SPL CRTRDGE MISS	
Possible Cause	Corrective Action
Sample cartridge missing during a run using Interactive Dilution Protocol.	<ol style="list-style-type: none"><li>1. Inspect the carousel and discard the affected cartridges and cuvettes.</li><li>2. Load the cartridge and cuvettes, ensuring that all sample cartridges are present.</li><li>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>

SPL SYR JAMMED SPL SYR NOT HME SPL SYR STP LOSS	
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Possible Cause	Corrective Action
Long-term nonuse with salt buildup. Faulty sample syringe seal. Valve malfunctioning. Dispenser failure. Liquid heater or probe plugged.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. <b>Replace sample syringe</b>.</li><li>3. Press <b>PRIME</b> three times. Ensure buffer is coming out of the tip of the probe.</li><li>4. <b>Replace valve block</b>.</li><li>5. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>



SPLVOL ILLEGAL

Possible Cause	Corrective Action
Attempting to perform <b>Dilution Protocol</b> for assay that does not have protocol available.	1. Press <b>STOP</b> .
Incorrect sample volume programmed into assay parameters for pipetting mode being used.	2. Refer to the assay manual insert for the correct sample volume required for the assay and for Dilution Protocol availability.
	3. <b>Edit sample volume parameter ASSAY XX.1</b> to correct volume.
	4. Proceed with test run.
Mode 1 must be .2 µL to 20 µL	
Mode 2 must be 2 µL to 180 µL	
Mode 3 must be 5 µL to 145 µL	
Mode 4 must be .2 µL to 20 µL	
Mode 5 must be .2 µL to 350 µL	
Mode 6 must be 20 µL to 350 µL	
Mode 7 must be 3 µL to 105 µL	
Mode 8 must be 2 µL to 175 µL	
Mode 9 must be 100 µL to 350 µL	
Mode 10 must be 5 µL to 175 µL	
Mode 11 must be 2 µL to 180 µL	
Mode 12 must be .2 µL to 350 µL	
Mode 17 must be .2 µL to 20 µL	
Mode 19 must be 2 µL to 180 µL	
Mode 21 must be .2 µL to 350 µL	
Mode 22 must be .2 µL to 350 µL	
Mode 23 must be 50 µL to 450 µL	
Mode 25 must be 2 µL to 20 µL	
Mode 26 must be .5 µL to 20 µL	
Mode 27 must be .5 µL to 20 µL	
Mode 28 must be 2 µL to 20 µL	
Mode 30 must be 2 µL to 180 µL	
Mode 31 must be .8 µL to 1.7 µL	
Mode 33 must be .2 µL to 20 µL*	
Mode 37 must be 2 µL to 180 µL	
Mode 40 must be 16 µL	
Mode 42 must be 2 µL to 20 µL	
Mode 43 must be 2 µL to 20 µL	

\*For Benzodiazepines Serum (Mode 33), sample volume must be .6 µL to 20 µL.

SPL NOT MONOT

Possible Cause	Corrective Action
This message will appear when <b>System 4.2</b> is used to redisplay calibration data and the polarization values did not change in a constant direction.	Refer to <b>SPLS NOT MONOTONIC</b> under Printed Error Codes.

SRAM ERR

**NOTE:** This code appears on the reagent display.

Possible Cause	Corrective Action
Internal self-diagnostic test failure.	<div><div>1. Press <b>STOP</b>.</div><div>2. Call the <b>Customer Support Center</b> with details.</div></div>

T LEFT = XX or XXX

T USED = XX or XXX

**NOTE:** Message appears in reagent display.

TEMP CAL FAIL

Possible Cause	Corrective Action
When running Temp Cal (Test 3.1):  Incorrect Temperature entered.  A large THM OFF value change was necessary.  Carousel moved during calibration.  Ambient temperature affected the degrees C entered.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Repeat Temp Cal (Test 3.1) with new cuvettes.</li><li>3. If unable to correct the problem, call the Customer Support Center.</li></ol>

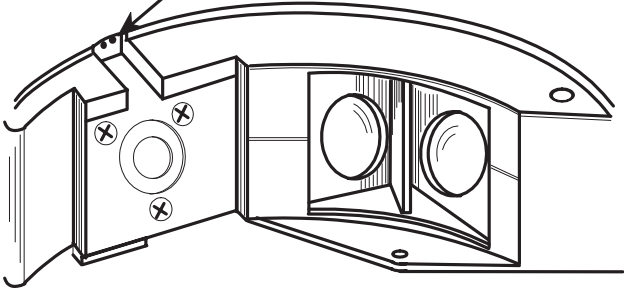
TEMP STABILIZING

Possible Cause	Corrective Action
If a heater is momentarily out of specification.	<ol style="list-style-type: none"><li>1. An informative message, no action necessary unless message persists.</li><li>2. Ensure all environmental specifications for the TDxFLx<sup>®</sup> Analyzer are being met.</li><li>3. If message continues, call the Customer Support Center.</li></ol>

TIME \_\_ . \_\_ . \_\_

Possible Cause	Corrective Action
Instrument power has just been turned on. Will occur after a momentary interruption of power.	<ol style="list-style-type: none"><li>1. Enter time of day, using military (24-hour) time and press <b>STORE</b>.</li><li>2. Display shows [READY], press <b>PRIME</b>.</li><li>3. Begin operation as necessary.</li></ol>

TOO FEW CUVETTES

Possible Cause	Corrective Action
Incorrect number of cuvettes for a calibration run.	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. Put correct number of cuvettes into carousel and lock it.</li><li>3. Ensure CAL REP assay parameter (.6) is set correctly for mode of operation (random access, batch, or unit dose).</li><li>4. Check the sample load list to ensure that the number of tests entered correspond to the number of tests on the carousel.</li><li>5. Remove any obstruction near the optical sensor. Clean the optical sensors on the optics assembly with a cotton swab. (The optical sensor is located inside the indentation along the top edge of the optics assembly.)</li></ol>
Incorrect number of cuvettes for a <b>Test 3</b> calibration procedure.	
Optical sensor dirty or obstructed.	
When running in unit dose or random access mode, the number of samples entered does not correspond to the number of cuvettes present on the unit dose carousel or sample loadlist.	
	<div><div>OPTICAL SENSORS</div></div>
	<ol style="list-style-type: none"><li>6. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>

TOO LITTLE RGT

Possible Cause	Corrective Action
Batch reagent pack empty.	1. Press <b>STOP</b> .
Vial cap liner left on top of vial.	2. Replace empty reagent batch pack and repeat run.
R-boom or Z-boom not properly positioned.	3. Remove the vial cap liner from the vial.
Probe failed to sense fluid properly.	4. Ensure that the probe is properly positioned by performing an <b>Automated Probe Positioning and Boom Calibration (Test 3.10)</b> and a <b>Reagent Carousel Calibration (Test 3.13)</b> .
Probe not attached in boom arm properly.	5. Ensure that the wedge reagent pack is seated properly.
<b>Batch-pack adapter</b> not properly seated.	6. If a problem occurs with the new reagent pack, wash and dry the probe. Check the probe attachment. If the problem is not solved by this, <b>replace the probe</b> .
During random access calibration run, volume is insufficient.	7. Check the <b>front to back probe position</b> using the probe positioning cartridge.
Wedge reagent pack not seated properly on the reagent carousel.	8. Ensure correct positioning of the <b>batch-pack adapter</b> .
	9. If unable to correct the problem, call the <b>Customer Support Center</b> .

> = **THRSHLD**

Possible Cause	Corrective Action
Occurs when <b>System 4.2</b> is used to recall assay data for an abused drug assay and <b>System 6.7</b> (T PRINT) is set at 1.	Refer to > = <b>THRESHOLD</b> under Printed Error Codes.

> **T**

Possible Cause	Corrective Action
Occurs when <b>System 4.2</b> is used to recall assay data for an abused drug assay and <b>System 6.7</b> (T PRINT) is set at 0.	Refer to > = <b>T</b> under Printed Error Codes.

UNEXPECTED SPL	
Possible Cause	Corrective Action
Liquid is detected in a sample cartridge which is part of a panel of tests, but not the first position of the panel.	Replace the sample cartridge and restart the run.
VALVE JAMMED VALVE NOT HME VALVE STEP LOSS	

Possible Cause	Corrective Action
Valve core frozen with dried buffer.	1. Press <b>STOP</b> .
Valve failure.	2. Press <b>PRIME</b> three times.
	3. If problem still occurs, <b>replace valve</b> assembly.
	4. If unable to correct the problem, call the <b>Customer Support Center</b> .

WRONG CAROUSEL	
Possible Cause	Corrective Action
Attempting to perform a <b>Photo Calibration, Photo Check</b> , or <b>Unit Dose</b> or Turbo <sup>®</sup> Assays with the reagent carousel on board.	1. Press <b>STOP</b> .
Faulty reagent carousel home sensor sensing the presence of the reagent carousel when it is not present during <b>Photo Check, Photo Calibration, Unit Dose</b> and Turbo <sup>®</sup> Assay runs.	2. Verify that the reagent carousel has been removed before attempting to run <b>Photo Calibration/Photo Check</b> or <b>Unit Dose</b> or Turbo <sup>®</sup> Assays.
	3. Clean the reagent carousel home sensor.
	4. If unable to correct the problem, call the <b>Customer Support Center</b> .

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**WRONG PAK TYP**


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Possible Cause	Corrective Action
No reagent pack in instrument.	1. Press <b>STOP</b> .
Reagent pack not seated properly.	2. Remove reagent pack. Wipe label to remove any dirt. Slide finger along to remove any air bubbles.
Label not clean on reagent pack.	3. Straighten vial insert in reagent pack or use new reagent pack.
Bubble under label on reagent pack.	4. Clean barcode reader with dampened cotton swab.
Reagent pack vial inserted crooked.	5. Edit <b>System 2.2</b> to “0”. Leave access door open and initiate run. Observe barcode reader as it reads the reagent pack label. If it turns on, red dots will show on the reagent pack label.
Barcode reader dirty.	6. Perform DAC Optimization procedure. Refer to <b>Section 5.0 Maintenance</b> .
Barcode reader unable to read label.	7. Use <b>Barcode Override procedure</b> .
Barcode reader starting in wrong position.	8. If problem occurs with all reagent packs, call the <b>Customer Support Center</b> .
Incorrect label on reagent pack.	

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**WRONG NUMBER**


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Possible Cause	Corrective Action
Nothing in memory corresponds to the number entered.	1. Press <b>STOP</b> .
	2. Continue editing parameters after confirming correct code number.
	3. Enter only carousel number 1 to 10 during <b>barcode override</b> .

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**WRT OVER BOUNDARY**


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Possible Cause	Corrective Action
Attempting to edit software that cannot be edited.	1. Press <b>STOP</b> .
	2. Call the <b>Customer Support Center</b> .

WRT PROTECT

Possible Cause	Corrective Action
Attempting to edit a parameter which cannot be edited.	<div><div>1. Press <b>STOP</b>.</div><div>2. Continue normal operation.</div></div>
Attempting to edit a curve fit parameter which is outside of the range (0 to 15).	
Attempting to edit <b>System 6.1</b> Serial #.	
	<div>Z BM JAMMED Z BM NOT HME Z BM STEP LOSS</div>

Possible Cause	Corrective Action
Possible obstruction preventing boom arm from moving vertically.	<div><div>1. Press <b>STOP</b>.</div><div>2. Look for obstruction and remove.</div><div>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

< or >

Possible Cause	Corrective Action
Attempting to edit a value which is outside the acceptable range for that parameter.	<div><div>1. Press <b>STOP</b>.</div><div>2. Continue normal operation after verifying value being edited.</div></div>
If symbol is in right side of display refer to the <b>Observed Problems</b> section under Display Shows Single Character.	



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AUTO BOOM CAL OUT OF SPEC

Possible Cause	Corrective Action
Z-boom step number not 172 or 173 for one or more positions, during Automated Probe Positioning and Boom Calibration (Test 3.10).	<div><div>1. Perform manual Boom Calibration (Test 3.2).</div><div>2. If unable to correct the problem, call the Customer Support Center.</div></div>

AVG I TOO LARGE

Possible Cause	Corrective Action
<div>During Photo Calibration Average Intensity measured was too large.</div> <div>Test 3.4 parameters do not match value on carousel label.</div> <div>Gain in Test 2.2.1 and Test 3.4.1 does not match label on X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel.</div> <div>Stray light causing interference with optical readings.</div> <div>Damaged or malfunctioning X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel.</div>	<div><div>1. Press STOP.</div><div>2. Print Test 3.4 and check that the gain (3.4.1), intensity (3.4.2) and polarization (3.4.4) values match the values on the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label.</div><div>3. Print Test 2.2 and check that the gain (2.2.1) value matches the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label.</div><div>4. Edit any parameters which do not match so that the instrument parameters are the same as the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label.</div><div>5. Rerun Test 3.4.</div><div>6. Check to be sure access door is properly seated. Also check that lamp cover is properly seated.</div><div>7. Check ampules in carousel for cracks or leaks. If found, order a new X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel (LN 9520-31).</div><div>8. If carousel has not been stored in box, place in box and rerun Photo Calibration in 1 hour.</div><div>9. Run normal assays. If controls are within range, proceed with reporting patient results. Notify the Customer Support Center.</div><div>10. If unable to correct the problem, call the Customer Support Center.</div></div>

AVG I TOO LARGE

Possible Cause	Corrective Action
<p>During <b>Pipet Check (Test 2.3)</b> the Average Intensity of locations 16-20 was greater than 10,000.</p> <p>Dispenser not functioning properly.</p> <p><b>Photo Calibration</b> performed with wrong parameters (<b>Test 3.4.1, 3.4.2</b> and <b>3.4.4</b>) in memory.</p>	<ol style="list-style-type: none"><li>1. Use another vial of Pipet Check Solution (LN 9531-02).</li><li>2. Check tubing and dispenser for leaks, slippage or buffer build-up.</li><li>3. Check to be sure access door is properly seated. Also check that lamp cover is properly seated.</li><li>4. Run <b>Photo Check (Test 2.2)</b>.</li><li>5. Run <b>Photo Cal (Test 3.4)</b>. Repeat <b>Photo Check (Test 2.2)</b>.</li><li>6. Repeat <b>Pipet Check</b>.</li><li>7. Replace dispenser components one at a time in the following order:<ol style="list-style-type: none"><li>a. <b>Probe</b></li><li>b. <b>Sample Syringe</b></li><li>c. <b>Diluent Syringe</b></li><li>d. <b>Valve Block</b></li></ol></li><li>8. Repeat <b>Pipet Check</b>.</li><li>9. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>

AVG I TOO SMALL

Possible Cause	Corrective Action
During <b>Photo Calibration</b> ( <b>Test 3.4</b> ), the Average Intensity measured was too small.	1. Press <b>STOP</b> .
<b>Test 3.4</b> parameters do not match value on label.	2. <b>Print Test 3.4</b> and check that the <b>gain (3.4.1)</b> , <b>intensity (3.4.2)</b> and <b>polarization (3.4.4)</b> values match the values on the X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel label.
<b>Gain in Test 2.2.1</b> and <b>3.4.1</b> does not match label on X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel.	3. <b>Print Test 2.2</b> and check that <b>gain (2.2.1)</b> value matches the X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel label.
Insufficient light reaching detector.	4. Edit any parameters which do not match so that the instrument parameters are the same as the X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel label.
Damaged or malfunctioning X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel.	5. Rerun <b>Test 3.4</b> .
	6. Check lamp to assure it is properly installed. Look for and remove any obstruction found on the lens on the left wall inside the lamp housing.
	7. <b>Replace the source lamp</b> .
	8. Check ampules in carousel for cracks or leaks. If found, order a new X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel (LN 9520-31).
	9. Run normal assays. If controls are within range, proceed with reporting patient results. Notify the <b>Customer Support Center</b> .
	10. If unable to correct the problem, call the <b>Customer Support Center</b> .

AVG I TOO SMALL

Possible Cause	Corrective Action
During <b>Pipet Check (Test 2.3)</b> , the Average Intensity of locations 16-20 was less than 4,000.	1. Use another vial of Pipet Check Solution (LN 9531-02).
Dispenser not functioning properly.	2. Check lamp to ensure it is properly seated. Look for and remove any obstruction found on the lenses, including the lens on the inside left wall of the source lamp housing.
Photo Cal performed with wrong parameters ( <b>Test 3.4.1, 3.4.2 and 3.4.4</b> ) in memory.	3. <b>Replace source lamp.</b>
	4. Run <b>Photo Check (Test 2.2)</b> .
	5. Run <b>Photo Cal (Test 3.4)</b> . Repeat <b>Photo Check (Test 2.2)</b> .
	6. Repeat <b>Pipet Check</b> .
	7. Replace dispenser components one at a time in the following order: <div><div>a. <b>Probe</b></div><div>b. <b>Sample Syringe</b></div><div>c. <b>Diluent Syringe</b></div><div>d. <b>Valve Block</b></div></div>
	8. Repeat <b>Pipet Check</b> .
	9. If unable to correct the problem, call the <b>Customer Support Center</b> .

AVG P TOO LARGE

Possible Cause	Corrective Action
During <b>Photo Calibration (Test 3.4)</b> , the Average Polarization measured was too large.	1. Press <b>STOP</b> .
<b>Test 3.4</b> parameters do not match value on label.	2. <b>Print Test 3.4</b> and check that the <b>gain (3.4.1)</b> , <b>intensity (3.4.2)</b> and <b>polarization (3.4.4)</b> values match the values on the X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel label.
Liquid crystal is not operating properly.	3. Edit any parameters which do not match so that the instrument parameters are the same as the X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel label.
Damaged or malfunctioning X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel.	4. Rerun <b>Test 3.4</b> .
	5. Check ampules in carousel for cracks or leaks. If found, order a new X SYSTEMS <sup>®</sup> Fluorometric Standards Function Test Set Carousel (LN 9520-31).
	6. Run normal assays. If controls are within range, proceed with reporting patient results. Notify the <b>Customer Support Center</b> .
	7. If unable to correct the problem, call the <b>Customer Support Center</b> .

AVG P TOO SMALL

Possible Cause	Corrective Action
<p>During <b>Photo Calibration (Test 3.4)</b>, the Average Polarization measured too small.</p> <p><b>Test 3.4</b> parameters do not match value on label.</p> <p>Liquid crystal not operating properly.</p> <p>Damaged or malfunctioning X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel.</p>	<ol style="list-style-type: none"><li>1. Press <b>STOP</b>.</li><li>2. <b>Print Test 3.4</b> and check that the <b>gain (3.4.1)</b>, <b>intensity (3.4.2)</b> and <b>polarization (3.4.4)</b> values match the values on the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label (LN 9520-31).</li><li>3. Edit any parameters which do not match so that the instrument parameters are the same as the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label.</li><li>4. Rerun <b>Test 3.4</b>.</li><li>5. Check ampules in carousel for cracks or leaks. If found, order a new X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel (LN 9520-31).</li><li>6. Run normal assays. If controls are within range, proceed with reporting patient results. Notify the <b>Customer Support Center</b>.</li><li>7. If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>

BACKGROUND TOO LARGE

Possible Cause	Corrective Action
During calibration, background intensity exceeded assay parameter XX.20 (MX BKG).	1. Check assay parameter XX.3 (BKG FAC) for the abused drug assay being run. If parameter XX.3 (BKG FAC) is set to 0, call the <b>Customer Support Center</b> for the proper value.
During calibration of an abused drug assay, parameter XX.3 (BKG FAC) is set to 0.	2. Open access door.
Door not closed.	3. Reseat lamp cover.
Parameter not correct.	4. Close door securely.
Failure to discard used cuvettes.	5. Ensure that <b>System 2.2</b> (Door Lock) parameter is set to 1.
Lamp cover not properly seated.	6. Check assay parameter XX.20 in the assay manual insert for assay being run. If it is not correctly programmed in the TDxFLx <sup>®</sup> Analyzer, edit the value to agree with the assay manual insert.
Inlet tube not seated all the way into buffer.	7. Push inlet tube all the way into buffer, press <b>PRIME</b> two or three times.
Reagents not in correct order, S, T, P.	8. Use new reagent pack and calibrators.
Contaminated buffer carton.	9. If problem occurs with more than one assay, use new container of buffer.
	10. Run <b>Pipet Check (Test 2.3)</b> .
	11. If unable to correct the problem, call the <b>Customer Support Center</b> .



BARCODE FAIL

Random Access

Possible Cause	Corrective Action
Reagent barcode reader not functioning properly.	1. Press <b>STOP</b> .
Reagent barcode reader dirty or not aligned.	2. Reseat reagent carousel.
Dirty or damaged barcode label.	3. Make sure all wedges are seated properly.
Barcode label not seated properly.	4. Clean barcode labels.
Wedge reagent pack not seated properly.	5. Clean reagent barcode reader.
Reagent carousel not functioning properly.	6. Check bottom of reagent carousel for damage or obstructions. Clean it if necessary.
Loose, damaged, or dirty motor gear.	7. Clean and dry the reagent carousel motor gear as needed.
	8. If barcode label is damaged, use <b>barcode override</b> .
	9. Perform <b>Reagent Carousel Calibration (Test 3.13)</b> .
	10. If unable to correct the problem, contact the <b>Customer Support Center</b> .

Unit Dose

Possible Cause	Corrective Action
Missing a unit dose cartridge.	1. Use the <b>Barcode Override procedure</b> .
Unit dose cartridge barcode label is misread by the barcode reader.	2. Perform <b>Unit Dose Boom Calibration (Test 3.6)</b> .
	3. Replace the cartridge causing the error.

BELOW 1

Possible Cause	Corrective Action
When running the Total T <sub>3</sub> PLUS assay with <b>System 6.8</b> (TOT T <sub>3</sub> ) set at 1, and the concentration is less than 1.0 ng/mL.	A message signifying that the result is less than 1.0 ng/mL. No action necessary.

BLK I HI ALERT

Possible Cause	Corrective Action
When running the CRP assay, a sample gives a BLK I reading greater than 1600.00 (MX BKG, parameter 53.20).	<div><div>1. These samples should not be diluted.</div><div>2. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

CAL REPS INCORRECT FOR CALIBRATION

Possible Cause	Corrective Action
<div>During calibration, correct number of samples were not detected. Correct number of samples = 6 times CAL REP, (assay parameter XX.6).</div> <div>Sample skipped on one or more calibrators.</div> <div>Wrong number of replicates put into sample cartridges.</div> <div>Probe not properly inserted into end of boom arm.</div> <div>Probe position not correct in sample or predilution well.</div>	<div><div>1. Set up carousel with sufficient cuvettes to run all samples. Ensure that at least the minimum sample volume is used in the sample well.</div><div>2. Prepare carousel with new calibrators, ensuring that pipettors are dispensing the minimum volume required accurately.</div><div>3. Wash and dry probe. <b>Check probe</b> to ensure it is properly attached in boom arm.</div><div>4. Press <b>PRIME</b> and observe dispenser for possible leaks or slipping syringe. Correct problem as applicable.</div><div>5. Run <b>Dispense Check (Test 6.3)</b> or observe <b>Buffer Run</b> for proper probe positioning and adjust as needed.</div><div>6. <b>Run Automated Probe Positioning and Boom Calibration, Test 3.10.</b></div><div>7. <b>Replace probe.</b></div><div>8. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

CALIBRATION ABORTED

Possible Cause	Corrective Action
During calibration, an error was encountered for each replicate of a calibrator level, therefore no concentration can be determined for that calibrator. No further calibrators, controls or samples will be pipetted.	<div><div>1. The error message(s) printed for the effected calibrator must first be addressed. See the appropriate section of this <b>troubleshooting guide</b>.</div><div>2. Repeat the calibration run, repipetting all calibrators and controls (using clean, previously unused cartridges and cuvettes).</div><div>3. If unable to correct the problem, contact the <b>Customer Support Center</b>.</div></div>

CHECK DATA

Possible Cause	Corrective Action
Either the T <sub>4</sub> or T-Uptake concentration was zero when calculating the FTI.	1. Check the T-Uptake units printed for the position.
Either the T <sub>4</sub> or T-Uptake position did not give a reasonable concentration.	2. Check the T <sub>4</sub> CONC printed on the previous assay for the position.
T-Uptake was not the next assay run after T <sub>4</sub> .	3. Rerun the samples in this position and calculate FTI by hand (see the T-Uptake assay insert in the assay manual insert for instructions on calculating the FTI).
The TDxFLx <sup>®</sup> Analyzer lost power between T <sub>4</sub> and T-Uptake runs.	4. If unable to correct the problem, call the <b>Customer Support Center</b> .

CHECK WASTE CUP

Possible Cause	Corrective Action
Normal message after approximately 25 prime cycles have been completed if <b>System 2.11</b> is set to 1.	1. Press <b>STOP</b> .
Number of prime cycles will be approximately 174 if <b>System 2.11</b> is set to 2.	2. Empty waste container.
	3. Replace waste container.

CHECKSUM ERROR WAS FOUND IN MEMORY BOARD ...

Possible Cause	Corrective Action
A defective NOVRAM in the memory (software module) board.	Call the <b>Customer Support Center</b> .
External power problems, e.g., surge.	

CHECKSUM ERROR WAS FOUND IN SYSTEM. ...

Possible Cause	Corrective Action
A defective NOVRAM in the CPU board (#2).	Call the <b>Customer Support Center</b> .
External power problems e.g., surge.	

CONCENTRATION LOW

Possible Cause	Corrective Action
For pipetting modes using Interactive Dilution Protocol: when the polarization value of a sample is compared to and is less than the sensitivity level.	See “Low Test Results” under the Observed Problems section.

CRV FIT ERR ###

Possible Cause	Corrective Action
Assay parameters incorrect. During calibration, data reduction for proper curve fitting was not acceptable. Probe damaged or positioned incorrectly. Dispenser system not working properly. Reagent not working properly due to improper storage or handling. Improper temperature operation. The following page contains a table that defines the curve fit error messages.	<div><div>1. Verify that the parameters are current (refer to the assays manual or to the most recent activation procedure).</div><div>2. Carefully inspect probe for damage or leakage. Replace probe if damaged.</div><div>3. Run Dispense Check (Test 6.3). Check for splashing in the predilution well of the unit dose cartridge. Observe probe positioning and correct if necessary.</div><div>4. Check all dispenser components (valve, syringes, tubing) for crimps, leaks or cracks. Replace components as needed.</div><div>NOTE: Remove syringes and check plungers for tightness in barrel. If a plunger is loose, replace the entire syringe.</div><div>5. Check dilution buffer level. If the buffer level is low or has been pooled, replace with fresh buffer and repeat calibration.</div><div>6. If unit dose cartridges and/or calibrators are expired or have been improperly stored or handled, repeat the calibration with fresh unit dose cartridges and/or calibrators.</div><div>7. Run Temperature Check (Diagnostic Test 2.1).</div><div>8. If unable to correct the problem, call the Customer Support Center.</div></div>

CRV FIT ERR ### (continued)

Possible Cause	Corrective Action
CRV FIT ERR MESSAGE DEFINITIONS	
CRV FIT ERR ###	CURVE CHARACTERISTICS
127	A mP too large
890	A-F span too large
132	A-B span too small
084	A-B span too large
395	B-C span too small
689	B-C span too large
257	C-D span too small
416	C-D span too large
990	D-E span too small
743	D-E span too large
660	E-F span too small
310	E-F span too large
Call the Customer Support Center for the curve characteristics of the effected assays.	

FAILED - RNG I OUT OF SPEC

Possible Cause	Corrective Action
A RNG I value is greater than or equal to 250.00 during a <b>Pipet Check</b> run.	1. Check for upside-down cuvettes, and repeat <b>Pipet Check (Test 2.3)</b> .
Upside-down cuvette.	2. Repeat <b>Pipet Check</b> using a new vial of Pipet Check solution.
Leaks or crimps in tubing.	3. Check for leaks or crimps in tubing. Secure tubing connections or <b>replace tubing</b> as necessary. Repeat <b>Pipet Check</b> .
Air bubbles in dispense system.	4. Check for air bubbles in dispense system and remove. Refer to Air Bubbles in Dispenser in the <b>Observed Problems</b> section. Repeat <b>Pipet Check</b> .
Buffer residue on carousel.	5. Wash and dry probe. Inspect for damage or wear and <b>replace</b> if necessary. Repeat <b>Pipet Check</b> .
Worn or damaged probe.	6. Wash any buffer residue on carousel, and repeat <b>Pipet Check</b> .
Leak in sample syringe.	7. <b>Replace probe</b> and perform the following procedures:
Leak in valve block.	a. <b>Automated Probe Positioning and Boom Calibration (Test 3.10)</b> .
Leak in diluent syringe.	b. 4-pot Boom Calibration <b>(Test 3.7)</b> , if applicable.
	c. Unit Dose Boom Calibration <b>(Test 3.6)</b> , if applicable.
	8. Repeat <b>Pipet Check</b> .
	9. <b>Replace sample syringe</b> , and repeat <b>Pipet Check</b> .
	10. <b>Replace valve block</b> , and repeat <b>Pipet Check</b> .
	11. <b>Replace diluent syringe</b> , and repeat <b>Pipet Check</b> .
	12. Recalibration of assays may be necessary after replacing probe, syringe, or valve block. Check to ensure that controls are in range.
	13. If error recurs, call the <b>Customer Support Center</b> .

HI OR LOW FOLLOWING CONCENTRATION RESULT

Possible Cause	Corrective Action
Sample value above (HI) or below (LOW) the programmed therapeutic range. (Assay parameters XX.3 and XX.4 programmed by the operator ).	Edit therapeutic range for assay if different range is desired. Refer to the assay manual insert for suggested expected results on individual assays.

HI AFTER BLK I RESULT

Possible Cause	Corrective Action
Sample blank reading was greater than programmed assay parameter XX.20 (MX BKG).	Are all samples affected? <ol style="list-style-type: none"><li>YES Check the following items and perform appropriate corrective action:<ol style="list-style-type: none"><li>Access door securely closed. Enable <b>System 2.2</b> by editing parameter to a value of 1.</li><li>Lamp housing cover properly seated.</li><li>Reagent vials in correct order S-T-P except T-Uptake which is P-T-P.</li><li>MX BKG properly programmed (parameter .20). Refer to the assay manual insert under the Assay Parameters section.</li><li>Install a new container of buffer.</li><li>Use a new reagent pack.</li></ol></li><li>NO - Proceed.</li></ol>
Door open while BLK I readings were taken.	Is the T <sub>4</sub> assay being run? <ol style="list-style-type: none"><li>YES - Repeat that sample ensuring a fresh cuvette is used. If it occurs again, dilute the sample with an equal amount of Calibrator A (0.0 ug/dL) and rerun, multiplying the result by the appropriate dilution factor.</li><li>NO - Repeat that sample ensuring a fresh cuvette is used. Concentration of sample can be reported if the BLK I reading is less than 3 times the MN TRACER (Assay parameter .21). If the BLK I exceeds 3 times the MN TRACER, prepare a manual dilution of the sample or run a <b>Dilution Protocol</b> and repeat that sample.</li></ol>
Reagent contamination.	
Buffer contamination.	
Failure to discard previously used cuvette.	

Possible Cause	Corrective Action
When running an REA <sup>®</sup> Assay, sample blank reading was greater than programmed assay parameter .20 (MX BKG).  Door open while FINAL V readings were taken.  Reagent contamination.  Failure to discard previously used cuvette.	<p>Are all samples affected?</p> <ol style="list-style-type: none"><li>YES  Check the following items and perform appropriate corrective action:<ol style="list-style-type: none"><li>Access door securely closed. Enable <b>System 2.2</b> by editing parameter to a value of 1.</li><li>Lamp housing cover properly seated.</li><li>Reagent vials in correct order S-T-P.</li><li>MX BKG properly programmed (parameter .20). Refer to the assay manual insert under the Assay Parameters section for the appropriate assay.</li><li>Buffer contaminated (use a new container).</li><li>P reagent contaminated (use a new reagent pack).</li></ol></li><li>NO - Proceed.</li><li>Repeat that sample ensuring a fresh cuvette is being used.</li><li>If unable to correct the problem, call the <b>Customer Support Center</b>.</li></ol>



HI INSTEAD OF CONCENTRATION

Possible Cause	Corrective Action
Sample mP value falls outside the mP value for the F calibrator.	Does the sample(s) follow a sample with an extremely high background? High-background samples are indicated by one or both of the following: <ul style="list-style-type: none"><li>– HI message prints after the BLK I result</li><li>– NET I SMALL message prints instead of concentration result</li></ul>
Incorrect probe positioning in predilution well.	1. YES Repeat the assay, ensuring that the sample(s) does not follow a high-background sample.
Liquid crystal not operating properly.	2. NO Dilute the sample manually, or perform the Dilution Protocol procedure, if available for the assay.
Improper carousel set-up or splashing of raw sample into predilution well.	<b>CAUTION: The Dilution Protocol procedure is only available for some assays. Refer to the appropriate assay manual insert to determine the dilution procedure for specific assays.</b>
Sample follows a sample with an extremely high background.	3. Set System 2.3 to 1 for automatic return of original SPL VOL (if available for that assay), or manually edit SPL VOL to original value at completion of assay. 4. Check for proper probe positioning in the predilution well if the assay is a Mode 2 or 3 pipetting sequence. Refer to Probe-Positioning Check and Adjustment using the probe-positioning cartridge. 5. Run Photo Check. If polarization values are less than 10, do not run Photo Calibration. Call the Customer Support Center.

\*\*\*HVCOEF RESET\*\*\*

Possible Cause	Corrective Action
Occurs if the HVCOEF has been automatically reset during a factory set (Test 6.2).	<div><div>1. Run a Photo Calibration (Test 3.4) and Photo Check (Test 2.2).</div><div>2. Run a Pipet Check (Test 2.3).</div><div>3. Run controls against the calibration curves to verify that the curves are still acceptable. Recalibrate if curves are unacceptable.</div></div>

ILLEGL MODE MIX

Possible Cause	Corrective Action
Barcode reader misread wedge reagent pack label as assay mode (XX.18) other than 1 or 17.  Assay entered using barcode override, of mode (XX.18) other than 1 or 17 during a random access run.	<div><div>1. Perform a reagent carousel calibration (Test 3.13).</div><div>2. Clean the barcode reader and wedge reagent pack label.</div><div>3. Ensure that during barcode override for random access runs the assay entered is for mode 1 or 17.</div></div>

ILLEGAL SAMPLE

Possible Cause	Corrective Action
During REV 0 PIPETTING mode, liquid was detected in a sample cartridge that should have been empty.	Repeat the assay run.

INSUFFICIENT SAMPLE

Possible Cause	Corrective Action
Minimum sample volume not detected.	1. Ensure that at least the minimum sample volume is present. Refer to the assay manual insert for minimum sample volume requirements.
No sample in sample well.	2. Wash and dry probe and perform Automated Probe Positioning and Boom Calibration (Test 3.10).
Probe positioning incorrect in sample well.	3. If unable to correct the problem, replace probe and perform an Automated Probe Positioning and Boom Calibration (Test 3.10).
	4. Perform a buffer run (Test 3.14 Buffer Run or Test 3.15 Batch Buffer Run) and observe probe positioning. If not correct, run an Automated Probe Positioning and Boom Calibration (Test 3.10) or edit the appropriate system parameter.
	5. Check carousel for a broken or warped rim using Liquid Level Sensing Adjustment procedure or Z-boom Calibration procedure.
	6. Remove the probe and flush the end of the boom arm with water. Thoroughly dry the spaces and reattach the probe.
	7. If unable to correct the problem, call the Customer Support Center.

INSUFFIC RGT

Possible Cause	Corrective Action
Wedge reagent pack empty or has reached its maximum number of tests.	1. Press STOP.
Reagent volume in the pack is not enough to complete the number of samples that have been flagged by this message.	2. If the pack is empty, replace it with a new one and repeat the run.
During barcode override, entering 13-digit barcode number of a previously used/empty wedge reagent pack.	3. Remove the samples and cuvettes that were flagged by the message and repeat the run.
	4. Ensure that the correct 13-digit barcode number is entered correctly during barcode override.
	5. If unable to correct the problem, call the Customer Support Center.

INVALID ASSAY

Possible Cause	Corrective Action
Assay has not been activated.	<div><div>1. Assay needs to be activated.</div><div>2. <b>Pipet check</b> needs to be performed.</div><div>3. Press <b>STOP</b>.</div><div>4. Reseat reagent pack.</div></div>
<b>Pipet Check</b> has not been performed.	
Barcode reader misread reagent pack label as assay that has not been activated.	<div><div>5. Check barcode reader or boom arm for obstruction and remove if found. Also check length of probe tubing.</div><div>6. Clean label on reagent pack and carousel with water-dampened cotton swab.</div><div>7. Clean barcode reader with water-dampened cotton swab.</div><div>8. Straighten vial insert in reagent pack or use a new reagent pack.</div><div>9. Use another carousel or reagent pack to see if problem still occurs.</div><div>10. Disable door lock, pressing <b>SYSTEM 2.2 EDIT 0 STORE STOP</b>. Place reagent pack with vial caps removed and the sample carousel into the instrument, leave access door open. Initiate a run and determine if error is occurring on carousel or reagent pack. Enable door lock, pressing <b>SYSTEM 2.2 EDIT 1 STORE STOP</b>.</div><div>11. Use <b>Test 4.4</b> to check boom-arm barcode reading performance (<b>SYSTEM</b> for reagent pack, <b>PRIME</b> for carousel).</div><div>12. Perform Boom Cal (<b>Test 3.2</b>).</div><div>13. Determine the white to black transition point and edit <b>System 3.12</b> and 3.13 as applicable.</div><div>14. Use <b>Barcode Override Procedure</b> if unable to correct problem.</div><div>15. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

INVALID BARCODE

Possible Cause	Corrective Action
Barcode label cannot be decrypted.	<div><div>1. Press <b>STOP</b>.</div><div>2. Use <b>barcode override</b>, and ensure that the 13-digit number is the same as that of the barcode label.</div><div>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

INVALID DATE

Possible Cause	Corrective Action
Invalid date was entered during factory set.	<div><div>1. Press <b>STOP</b>.</div><div>2. Press <b>SYSTEM 1.1 EDIT</b>. Enter valid date.</div></div>

LIQ LEVEL HI

Possible Cause	Corrective Action
<div>Splashing during pipetting increased the volume of liquid in the predilute well.</div> <div>A drop of liquid forming a bridge between the electrodes of the probe.</div>	<div><div>1. Wash and dry probe and perform an <b>Automated Probe Positioning and Boom Calibration (Test 3.10)</b>.</div><div>2. If unable to correct the problem, <b>replace probe and electrodes</b> and perform an <b>Automated Probe Positioning and Boom Calibration (Test 3.10)</b>.</div><div>3. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

LIQ LEVEL LO

Possible Cause	Corrective Action
<div>The reagent level is insufficient in one of the unit dose cartridges.</div> <div>The Z-boom Calibration is incorrect. Usually occurs on several cartridges on same run or on a regular basis.</div> <div><b>System 8.9</b> may be set incorrectly; should be 300.</div> <div><b>System 8.10</b> may be set incorrectly; should be 137.</div>	<div><div>1. Replace the cartridge causing the error.</div><div>2. Perform a Z-boom Calibration (<b>Test 3.5</b>).</div><div>3. Perform a Unit Dose Boom Calibration (<b>Test 3.6</b>).</div><div>4. Edit <b>System 8.9</b> to 300 and <b>System 8.10</b> to 137 if necessary.</div><div>5. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

LIQ SENSE ERROR

Possible Cause	Corrective Action
Film or bubble present in reagent vials.	1. Check for bubbles and remove with an applicator stick.
During Dispense Check (Test 6.3) or Buffer Run, too much buffer is added to the empty vials.	2. Remove some of the buffer from the buffer pack and repeat run (2-3 mL should be sufficient).
Splashing occurred when dispensing into the predilute or cuvette just prior to moving to the reagent well to aspirate reagent.	3. Flush the waste/wash station with deionized water (Section 5.0 Maintenance) to remove any salt deposits through the waste system.
Bubbles in the dispenser system forming a bridge between the electrodes of the probe as it moves toward the reagent well.	4. Perform Probe Wash with deionized water as described in Section 5.0 Maintenance.
Splashing in the waste/wash station.	5. Check for leaks or bubbles in the dispensing system. Replace parts as appropriate.
	6. Perform the Probe-Positioning Check and Adjustment procedure using the probe positioning cartridge.
	7. If unable to correct the problem, call the Customer Support Center.

LIQUID XTAL FAILURE

Possible Cause	Corrective Action
Test 3.4.4 parameter incorrect.	1. Check Test 3.4.4 to be sure it matches the value on the X SYSTEMS® Fluorometric Standards Function Test Set Carousel.
Liquid crystal polarizer malfunctioning.	2. Run Photo Check (Test 2.2).
	3. If unable to correct the problem, call the Customer Support Center.

Possible Cause	Corrective Action
Thumbscrew washer missing.	1. Wash and dry probe. Verify the presence of a nylon washer between the thumbscrew and the metal bar on the boom arm.
Liquid-level sense failure during the second pipetting revolution.	2. Check cuvettes to be sure they were empty when the run was initiated.
Liquid on probe is creating a liquid bridge between two electrodes.	3. Push tube all the way into buffer bottle.
Probe tip damaged or mispositioned.	4. <b>Replace the buffer</b> if empty. Refer to Buffer Platform Adjustment Procedure under <b>Section 5.0 Maintenance</b> , if necessary.
Splashing in the predilution well.	5. Press <b>PRIME</b> three times, checking for air bubbles. If air bubbles are present, refer to <b>AIR BUBBLES IN DISPENSER</b> under Observed Problems.
Buffer salt bridge has formed between two electrodes.	6. Remove the probe and wash the front end of the boom arm with water. Thoroughly dry the spaces in the boom. Verify the presence of a nylon washer between the thumbscrew and the metal bar on the boom arm.
Used cuvettes not removed from carousel.	7. Reattach the probe. Ensure probe is pushed upwards completely against the boom arm and that the thumbscrew is secure but not overtight.
Inlet tube not seated all the way into buffer.	8. Observe a <b>buffer run</b> . <b>Check the probe alignment</b> . If necessary, perform <b>Automated Probe Positioning and Boom Calibration (Test 3.10)</b> .
Undetected empty buffer bottle.	9. If unable to correct the problem, call the <b>Customer Support Center</b> .
Probe thumbscrew not properly secured.	
Liquid-level-sensing electrodes not properly inserted into end of boom arm.	

LOW INSTEAD OF CONCENTRATION

Possible Cause	Corrective Action
mP reading value higher than the mP used in the calibration curve for the A calibrator.	Are all samples effected?
Assay run without calibration curve in memory.	1. YES - Check to be sure calibration curve is in memory and correct reagent pack is being used before performing the assay. Check to make sure the carousel label was read properly and that a Calibration carousel was used to calibrate the assay. Observe a <b>buffer run</b> for proper probe positioning.
Assay run with wrong type reagent pack.	2. NO - Repour sample, assuring no air bubbles are trapped, then repeat assay. If low result for a sample is repeated, report out as less than sensitivity of the assay, referring to the assay manual insert for that assay.
Air bubble trapped in sample.	
Incorrect probe positioning in predilution well.	
Calibration carousel label not read correctly or wrong carousel used to calibrate the assay.	
	> MX BKG

Possible Cause	Corrective Action
When performing an abused drug assay, this message appears instead of the concentration if BLK I is greater than assay parameter XX.20 (MX BKG), regardless of the <b>System 6.7</b> (T PRINT) setting.	Check assay parameter XX.3 (BKG FAC) for the abused drug assay being run. If parameter XX.3 is set to 0, call the <b>Customer Support Center</b> for the proper value.
During an abused drug assay run, parameter XX.3 (BKG FAC) is set to 0.	<b>WARNING: The patient sample must not be diluted and rerun. Assay parameter XX.20 (MX BKG) should not be edited to a greater value than is found for that assay in the Assay Parameters section of the assay manual insert.</b>



Possible Cause	Corrective Action
During calibration, net intensity was greater than or equal to 25.5 times assay parameter .21 (MN TR).	1. Press <b>PRIME</b> and observe dispenser for possible leaks or slipping sample syringe. Ensure that buffer is being dispensed through probe. Correct problem as applicable.
Dispenser system not working properly.	2. Examine <b>probe</b> carefully for damage. Ensure that the sample probe is approximately 1 mm longer than the liquid-level sensors. <b>Replace</b> if necessary. <b>Check front to back probe positioning.</b>
Reagent not working properly due to improper storage or handling.	3. Check for bubbles in each reagent vial. Remove bubbles and rerun.
Expired or contaminated pipet check solution.	4. Use a new reagent pack.
Assay not activated after installing new memory board.	5. If problem occurs with more than one assay, use new container of buffer.
Faulty source lamp.	6. Verify the reagent pack label was read correctly on the calibration printout.
Factory set not properly performed.	7. Check the MN TR (XX.21) to ensure it is greater than fifty. If it is less than fifty, use <b>System 5.1</b> to activate assay parameters. Contact the <b>Customer Support Center</b> for necessary codes.
Assay not properly activated.	8. Check the accuracy of the optics by performing Photo Check ( <b>Test 2.2</b> ). Perform Photo Cal ( <b>Test 3.4</b> ) if necessary.
	9. Run Pipet Check ( <b>Test 2.3</b> ) with fresh pipet check solution (LN 9531-02).
	10. Check proper positioning of source lamp in housing. <b>Replace lamp</b> , if necessary.
	11. If unable to correct the problem, call the <b>Customer Support Center</b> .

Possible Cause	Corrective Action
During an assay run, net intensity was less than assay parameter .21 (MN TR).	<div><div><div>1. Ensure that all cuvettes are right side up.</div><div>2. Repeat assay.</div></div></div>
Cuvette upside down.	<div><div><div><b>WARNING: Samples immediately adjacent to an upside-down cuvette or following a sample with an extremely high background may give erroneous results because of splashing or potential carryover. Repeat these samples.</b></div></div></div>
Dispenser system not working properly.	<div><div><div>3. Check that sample syringe retainer is secure. Observe dispenser for possible leaks. Ensure that buffer is being dispensed through probe.</div></div></div>
Reagent not working properly due to improper storage or handling.	<div><div><div>4. Examine probe for damage. Ensure that the delivery probe is approximately 1 mm longer than the liquid-level-sensing probes.</div></div></div>
Sample had an extremely high background.	<div><div><div>5. Check for bubbles in T vial. Remove bubbles and rerun.</div></div></div>
An REA <sup>®</sup> Chemistry has detected an extremely high concentration of analyte in a sample.	<div><div><div>6. Use fresh reagent pack (do not dilute or pool reagents).</div></div></div>
Assay was not activated after installing new memory board.	<div><div><div>7. Manually dilute sample 1:1 and repeat using <b>Dilution Protocol</b> or off-line dilution.</div></div></div>
	<div><div><div>8. If running an REA<sup>®</sup> Chemistry, check the cuvette for a more intense coloration compared to other samples. If the color is more intense, repeat the sample using the <b>Dilution Protocol</b>.</div></div></div>
	<div><div><div>9. If problem effects more than one assay, use a new container of X SYSTEMS<sup>®</sup> Dilution Buffer.</div></div></div>
	<div><div><div>10. Verify the reagent pack label was read correctly on the assay printout.</div></div></div>
	<div><div><div>11. Check the MN TR (XX.21) to ensure it is greater than fifty. If it is less than fifty, use <b>System 5.1</b> to activate assay parameters. Contact the <b>Customer Support Center</b> for activation codes.</div></div></div>
	<div><div><div>12. Check proper positioning of lamp in housing. <b>Replace lamp</b> if necessary.</div></div></div>
	<div><div><div>13. Run a Photo Check (<b>Test 2.2</b>). Perform Photo Cal (<b>Test 3.4</b>) if necessary.</div></div></div>
	<div><div><div>14. Run Pipet Check (<b>Test 2.3</b>) with fresh Pipet Check solution (LN 9531-02).</div></div></div>
	<div><div><div>15. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div></div>

## NET I TOO SMALL

Possible Cause	Corrective Action
During calibration, net intensity was less than assay parameter .21 (MN TR).	1. Set up new carousel with all cuvettes properly oriented.
Cuvette upside down in carousel.	2. Press <b>PRIME</b> and observe dispenser for possible leaks or slipping sample syringe. Ensure that buffer is being dispensed through probe. Correct problem as applicable.
Dispenser system not working properly.	3. Examine <b>probe</b> carefully for damage. Ensure that the sample probe is approximately 1 mm longer than the liquid-level sensors. <b>Replace</b> if necessary. <b>Check front to back probe positioning.</b>
Reagent not working properly due to improper storage or handling.	4. Check for bubbles in each reagent vial. Remove bubbles and rerun.
Expired or contaminated pipet check solution.	5. Use a new reagent pack.
Assay not activated after installing new memory board.	6. If problem occurs with more than one assay, use new container of buffer.
Faulty source lamp.	7. Verify the reagent pack label was read correctly on the calibration printout.
Assay not properly activated.	8. Check the MN TR (XX.21) to ensure it is greater than fifty. If it is less than fifty, use <b>System 5.1</b> to activate assay parameters. Contact the <b>Customer Support Center</b> for necessary codes.
	9. Check the accuracy of the optics by performing Photo Check ( <b>Test 2.2</b> ). Perform Photo Cal ( <b>Test 3.4</b> ) if necessary.
	10. Run Pipet Check ( <b>Test 2.3</b> ) with fresh solution (LN 9531-02).
	11. Check proper positioning of source lamp in housing. <b>Replace lamp</b> , if necessary.
	12. If unable to correct the problem, call the <b>Customer Support Center</b> .

NO AIR SPACE

Possible Cause	Corrective Action
Appears when probe does not detect an air space between the foil and the reagent fluid level of a unit dose cartridge.	1. Realign probe by performing a Unit Dose Boom Calibration (Test 3.6).
Bubbles in the reagent wells or reagent wells over filled.	2. Check the probe positioning and foil puncture in the reagent wells. Correct if necessary.
TEFLON <sup>®</sup> Coating worn on the fluid-sensing electrodes.	3. If isolated to one cartridge, replace cartridge.
Probe not able to complete puncture of foil within allotted time according to System 8.9 UD WAIT.	4. Check the condition of the TEFLON <sup>®</sup> Coating on the electrodes. If worn, replace electrodes.
Probe misaligned - electrodes too close to reagent well edge.	5. Perform a Z-boom Calibration (Test 3.5).
Probe weight loose.	6. Check tightness of mounting screws of boom arm weight and tighten if necessary.
	7. If unable to correct the problem, call the Customer Support Center.

NO AVG AVAILABLE

Possible Cause	Corrective Action
During calibration or assay run with sample replicates of 2 or more, one or more samples resulted in NET I SMALL so no average was possible.	1. Refer to NET I SMALL under Printed Error Codes.
Occurs when running an abused drug assay, with System 6.7 (T PRINT) set at 1, SPL REPS set at 2 or more, and one or more samples resulted in HI or LOW.	2. If running an abused drug assay set System 6.7 to 0 and reprint the data by pressing SYSTEM 4.1 RUN. One or more positions in the group showing NO AVG AVAILABLE should print HI or LOW.

NO FOIL FOUND

Possible Cause	Corrective Action
The probe is poorly positioned and the electrodes miss the reagent well completely.	1. Check the unit dose cartridge causing the error to ensure that the foil is intact. If it is, perform a Z-boom Calibration (Test 3.5).
The fluid-sensing electrodes are malfunctioning.	2. Check the position of the probe and correct as necessary, using Probe-Positioning Check and Adjustment procedure for TEFLON <sup>®</sup> Coated stainless steel probe in Section 5.0 Maintenance. Check System 8 parameters against the System 8 parameter printout received with the instrument.
	3. Perform a Unit Dose Boom Calibration (Test 3.6).
	4. Replace the fluid-sensing electrodes per instructions in Section 5.0 Maintenance.
	5. If unable to correct the problem, call the Customer Support Center.

NO RGT LOADED

Possible Cause	Corrective Action
Entering an assay number that does not have a corresponding wedge reagent pack on the reagent loadlist.	1. Re-enter assay number carefully ensuring that the number corresponds to one of the assays loaded on reagent carousel.
	2. Ensure that reagent loadlist is the one desired.
	3. If unable to correct the problem, call the Customer Support Center.

NO SAMPLES PIPETTED

Possible Cause	Corrective Action
During calibration or assay, no liquid was detected in any of the sample cartridges.	1. Set up a new carousel ensuring the correct volume is used and re-run.
Too little sample in sample cartridges.	2. If problem continues, wash and dry probe.
Probe not detecting fluid properly.	3. Perform Automated Probe Positioning and Boom Calibration (Test 3.10).
Probe positioned incorrectly in sample well or predilution well.	4. Check liquid-level sensing of electrodes using Test 4.4.
Liquid-level-sensing electrodes not properly inserted into end of boom arm.	5. Check probe attachment to end of boom arm. Ensure that thumbscrew is secure.
	6. Remove the probe and flush the front end of the boom arm with water. Thoroughly dry the spaces and reattach the probe.
	7. Replace probe. Perform an Automated Probe Positioning and Boom Calibration (Test 3.10).
	8. If unable to correct the problem, call the Customer Support Center.

NO VALID ANSWER

Possible Cause	Corrective Action
When using the Interactive Dilution Protocol, the units are edited to an inappropriate unit; this message will print instead of a concentration.	<div><div>1. Ensure that the units parameter XX.13 is set at the appropriate value indicated in the assay manual insert before attempting Interactive Dilution Protocol.</div><div>2. Manually dilute the sample with X SYSTEMS<sup>®</sup> Dilution Buffer or drug-free normal human serum and rerun using the Interactive Dilution Protocol.</div></div>
When using the Interactive Dilution Protocol, the concentration of a sample falls between dilution ranges, or none of the net polarizations for a sample are within the calibration curve; this message will print instead of a concentration.	
When using the Interactive Dilution Protocol, an error such as an upside down cuvette, <b>NET I SMALL</b> , <b>PREDIL LEVEL LOW</b> , <b>INSUFFIC SAMPLE</b> , <b>PIPETTE ERROR</b> or <b>SAMPLE CARTRIDGE MISSING</b> prints instead of a NET P value, and NO VALID ANSWER prints instead of a concentration.	

NONE DETECTED

Possible Cause	Corrective Action
Running an abused drug assay with <b>System 6.7</b> (T PRINT) set at 1, and the concentration is less than the threshold value specified in assay parameter .4 (THRSHLD).	No corrective action is required as this is not an error code but a message signifying that the result is less than the stored threshold. This message will appear instead of the result and no NET P or BLK I values will print.

NOT CALIBRATED

Possible Cause	Corrective Action
Printed in the assay header when a random access or a unit dose assay is run without calibrating the assay. The assay will still run but no concentration values will be printed.	<div><div>1. Calibrate the assay for the appropriate mode.</div><div>2. Rerun the samples.</div><div>3. If unable to correct the problem, call the Customer Support Center.</div></div>

NOVRAM X BAT LOW

Possible Cause	Corrective Action
During power-up checks, this message will appear if the battery is low. Power-up will continue.	Call the Customer Support Center.

\*\*\*PBIAS RESET\*\*\*

Possible Cause	Corrective Action
Occurs if the PBIAS has been automatically reset during a factory set (Test 6.2).	<div><div>1. Run a Photo Check (Test 2.2).</div><div>2. Run controls against the calibration curves to verify that the curves are still acceptable. Recalibrate if curves are unacceptable.</div></div>

PHO CHECK GAIN MUST MATCH CAL GAIN

Possible Cause	Corrective Action
During Photo Check or Photo Cal, Test 2.2.1 did not match Test 3.4.1.	Edit Test 2.2 and Test 3.4 parameters to match values on X SYSTEMS® Fluorometric Standards Function Test Set Carousel.



PIPETTE ERROR

Possible Cause	Corrective Action
Sampling or pipetting error.	1. Make sure that correct volume of sample is in the sample well.
Syringes not functioning.	2. Observe the dispensing process with a <b>buffer run</b> . If probe position is not correct, perform an <b>Automated Probe Positioning and Boom Calibration (Test 3.10)</b> or edit the appropriate system parameter.
	3. Observe syringe movement during a <b>buffer run</b> . Look for any obstructions or improper movement.
	4. If unable to correct the problem, call the <b>Customer Support Center</b> .

PO TOO SMALL

Possible Cause	Corrective Action
During calibration, polarization measured for calibrator A was less than assay parameter .16 (MN POLA).	1. Set up a new carousel assuring that calibrators are put in correct order with the proper number of replicates.
Wrong calibrator in first sample wells.	2. Perform the <b>Probe-Positioning Check and Adjustment procedure</b> using the probe-positioning cartridge to define the correct <b>System 3.4</b> parameter, if necessary.
Reagents have been stored incorrectly.	3. Ensure that the assay is properly activated.
Probe positioning incorrect in predilution well.	4. Use new reagent pack.
	5. Use new buffer.
	6. If problem occurs with more than one assay, use new container of buffer.
<b>NOTE:</b> For T-Uptake, polarization measured for calibrator F was less than assay parameter .16 (MN POLA).	7. If unable to correct the problem, call the <b>Customer Support Center</b> .

PREDIL LEVEL HI

Possible Cause	Corrective Action
Predilution well overfilled.	1. Check predilution well for overfilling.
Reuse of sample cartridges.	2. Verify that used sample cartridges are discarded.
	3. Perform an Automated Probe Positioning and Boom Calibration (Test 3.10).
	4. If unable to correct the problem, call the Customer Support Center.

PREDIL LEVEL LO

Possible Cause	Corrective Action
Sample not being sensed in predilution well.	1. Run a buffer run to verify that the appropriate amount of diluent is present in the predilution well.
	2. Press PRIME and observe for leaks or crimps in the tubing.
	3. Ensure the syringes are clamped properly.
	4. Ensure buffer is being dispensed from the probe. If buffer is not being dispensed, check the tubing connection. Replace the valve block.
	5. Check the probe attachment on the end of the boom arm. Ensure the thumbscrew is secure.
	6. Remove the probe and flush the front end of the boom arm with deionized water. Thoroughly dry the spaces and reattach the probe.
	7. Perform an Automated Probe Positioning and Boom Calibration (Test 3.10).
	8. If unable to resolve the problem, replace the probe and perform an Automated Probe Positioning and Boom Calibration (Test 3.10).
	9. If unable to correct the problem, call the Customer Support Center.

## RANGE TOO LARGE

Possible Cause	Corrective Action
During calibration, difference in polarization or percent fluorescence intensity between replicates of calibrators was greater than assay parameter .15 (MX DEV).	1. Check assay parameter .15 for correct value (See the assay manual insert for assay being run). If incorrect, edit to the proper value.
Air bubble in sample well or reagent vials.	2. Wash and dry probe. Check for damage.
Splashing of sample into predilution well while loading cartridges.	3. Inspect the sample carousel carefully to ensure all the locking tabs are in place. If a locking tab is missing, the cuvette will not be held securely. Discard the carousel and order a replacement.
Calibrators not put into sample cartridges in correct number of replicates.	4. Check calibrator replicates for proper loading. Remove all bubbles in the reagent vials and sample wells with applicator sticks.
Calibrators not put in correct order with reps sequential on the carousel.	5. Prepare carousel with new calibrators.
Probe dirty, damaged, or positioned incorrectly.	6. Observe probe positioning and dispensing. Perform a <b>buffer run</b> . Adjust as necessary. Check dispensing system for leaks, crimps, bubbles or loose syringe retainer. <b>Replace as necessary</b> .
Reagent not responding properly.	7. Perform a <b>Probe Carryover Check (Section 4.0)</b> . If carryover is over 1.5% <b>replace the probe</b> according to <b>Section 5.0 Maintenance</b> .
Dispense system not functioning properly. Bubbles in the syringes or tubing.	8. Reseat the inlet tube into buffer. If unable to correct the problem, use a new container of buffer.
Inlet tube not seated all the way into buffer.	9. Reenable door lock ( <b>System 2.2</b> ) and repeat run.
Door opened with <b>System 2.2</b> disabled during run.	10. Perform <b>Photo Check (Test 2.2)</b> and take appropriate action.
Assay parameter .15 (MX DEV) not set correctly.	11. Perform <b>Pipet Check (Test 2.3)</b> and take appropriate action.
	12. <b>Replace probe</b> , perform <b>Automated Probe Positioning and Boom Calibration (Test 3.10)</b> , and <b>Reagent Carousel Calibration (Test 3.13)</b> .
	13. If performing an assay that requires pretreatment of a sample, check the accuracy of the pipettors.
	14. <b>Replace syringes</b> , and <b>valve block</b> .
	15. Use a new reagent pack.
	16. If the problem persists, call the <b>Customer Support Center</b> .

REAGENT LEVEL LO

Batch	
Possible Cause	Corrective Action
Reagent reaches unacceptable level during run.	<div><div>1. Ensure that probe is properly positioned by performing an Automated Probe Positioning and Boom Calibration (Test 3.10).</div><div>2. Replace reagent pack and repeat run.</div><div>3. If unable to correct the problem, call the Customer Support Center.</div></div>
Random Access	
Possible Cause	Corrective Action
Reagent reaches unacceptable level during the run.	<div><div>1. Ensure that the probe is properly positioned by performing Reagent Carousel Calibration (Test 3.13).</div><div>2. Replace the wedge reagent pack and repeat the run.</div><div>3. If unable to correct the problem, call the Customer Support Center.</div></div>

RGNT TOO FULL

Possible Cause	Corrective Action
Vial not seated fully down into pack.	<div><div>1. Press STOP.</div><div>2. Remove reagent carousel from instrument.</div><div>3. Break liquid film over vial opening.</div><div>4. Firmly push vial down into wedge pack. Insert wedge reagent pack on carousel, and place carousel into instrument.</div><div>5. Wash and dry probe.</div><div>6. Ensure that the probe is properly positioned by performing an Automated Probe Positioning and Boom Calibration (Test 3.10) and a Reagent Carousel Calibration (Test 3.13).</div><div>7. Push inlet tube all the way into the buffer.</div><div>8. Press PRIME three times, checking for air bubbles.</div><div>9. Remove the probe and flush the end of the boom arm with deionized water. Thoroughly dry with a tissue, and reattach the probe.</div><div>10. Perform an Automated Probe Positioning and Boom Calibration (Test 3.10).</div><div>11. Perform a buffer run. Observe probe position and adjust as needed.</div><div>12. If unable to correct the problem, call the Customer Support Center.</div></div>
Liquid film or air bubbles in vial opening.	
Wedge reagent pack not seated properly.	
Buffer salt bridge formed between electrodes.	
Inlet tube not seated all the way into buffer.	
Probe and liquid-level sensors not properly seated in end of boom arm.	
Probe thumbscrew loose.	
Boom-arm connectors dirty.	
R-boom or Z-boom not properly positioned.	

RGT DATABAS INIT

Possible Cause	Corrective Action
Failure in NOVRAM memory, where data information about reagents is stored, has caused all data to be lost.	<div><div>1. Press <b>STOP</b>.</div><div>2. Call the <b>Customer Support Center</b>.</div></div>
Database will be initialized and reset for future storage.	

SAMPLE LEVEL HI

Possible Cause	Corrective Action
Sample well filled too high.	<div><div>1. Ensure an appropriate volume of sample is present in the sample well.</div><div>2. Inspect the surface of the sample well for bubbles and remove any bubbles with applicator stick.</div><div>3. Perform a <b>Z-boom Calibration (Test 3.5)</b>.</div><div>4. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>
Z-boom home incorrectly positioned.	
Bubbles present in sample well.	

SAMPLE LEVEL LO

Possible Cause	Corrective Action
Sample volume reaches an unacceptable level during run.	<div><div>1. Ensure that an appropriate amount of sample is present in the sample well.</div><div>2. Check the probe attachment on the end of the boom arm. Ensure the thumbscrew is secure.</div><div>3. Perform an <b>Automated Probe Positioning and Boom Calibration (Test 3.10)</b>.</div><div>4. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

SPAN LESS THAN MIN SPAN

Possible Cause	Corrective Action
Assay not activated.	1. Ensure that the assay is properly activated and that assay parameter XX.17 was edited appropriately.
During calibration, difference in either polarization or percent fluorescence intensity between A and F calibrators was less than assay parameter XX.17, MN SPAN.	2. Set up new carousel with calibrators in correct order.
	3. Ensure assay parameter XX.5 (CAL VOL) is set to the correct value for the reagent system being used. Refer to the assay manual insert.
A and/or F calibrators not in correct position.	4. Ensure assay parameter XX.6 (CAL REPS) is set to 2, if performing a batch or random access calibration run.
Improperly sampled F calibrator.	5. Use correct reagent pack for calibrator set.
	6. Reseat tube in buffer container.
Tube not seated all the way into buffer.	7. Observe a <b>buffer run</b> for proper probe positioning in predilution well.
Probe damaged or positioning incorrect.	8. Press <b>PRIME</b> and observe dispenser for possible leaks or slipping sample syringe. Correct problem as applicable.
Reagent not working due to improper storage or handling.	9. Use new container of buffer.
Wrong calibrators used for reagent system.	10. Perform <b>Photo Check</b> and take appropriate action.
	11. If unable to correct the problem, call the <b>Customer Support Center</b> .

SPL CRTRDGE MISS

Possible Cause	Corrective Action
Sample cartridge missing during a Methotrexate assay run using Interactive Dilution Protocol.	1. Inspect carousel for any positions missing a sample cartridge. Replace the sample cartridge and rerun the samples.
	2. If unable to correct the problem, call the <b>Customer Support Center</b> .

SPLS NOT MONOTONIC

Possible Cause	Corrective Action
During calibration, polarization or percent fluorescence intensity values were not in descending order. (For T-Uptake or other assays where specified, in ascending order.)	1. Set up a new carousel assuring calibrators are in correct order and replicated properly.
Calibrators not in correct alphabetical order.	2. Wash and dry probe. Inspect for damage.
Sample volume incorrect on one or more calibrators.	3. Press <b>PRIME</b> and observe dispenser for possible leaks or slipping sample syringe. Correct problem as applicable.
Calibrator concentrations incorrect.	4. Calibrate another assay and check for proper operation. If second assay works properly, rerun first assay using new set of calibrators.
Assay parameter .14 (CRV FIT) programmed incorrectly.	5. If more than one assay exhibits problems, <b>replace probe</b> according to <b>Section 5.0 Maintenance</b> .
	6. Verify the CRV FIT (X.14) parameter is programmed correctly. Refer to the appropriate assay section of the assay manual insert.
	7. If unable to correct the problem, call the <b>Customer Support Center</b> .

SPLVOL ILLEGAL

Possible Cause	Corrective Action
Occurs during unit dose runs when sample volume and calibrator volume are not the same.	1. Check assay parameters XX.1 (SPL VOL) and XX.5 (CAL VOL) making sure they are correct. If they are not, edit the appropriate parameter. Refer to the appropriate assay section of the assay manual insert.
Occurs when trying to perform <b>dilution protocol</b> on unit dose assays or on an assay where Dilution Protocol is not available.	2. Do not attempt dilution protocol for unit dose assays. <b>NOTE:</b> The assay run will be completed, only those sample volumes that are illegal will be flagged. The flagged positions will not be assayed.
Occurs during a specific proteins assay run if assay parameters XX.5 (CAL VOL) and XX.7 - XX.12 (CONC A - CONC F) are set to 0.	3. Check the Specific Proteins Calibrators package insert for the correct value of parameters XX.5 (CAL VOL) and XX.7 - XX.12 (CONC A - CONC F). Edit the value(s) to agree with the package insert.
	4. If unable to correct the problem, call the <b>Customer Support Center</b> .

TEMP CAL FAIL

Possible Cause	Corrective Action
When running Temp Cal (Test 3.1): <div><div>a. Incorrect temperature entered.</div><div>b. A large THM OFF value change was necessary.</div><div>c. Carousel moved during calibration.</div><div>d. Ambient temperature affecting the degrees C entered.</div></div>	<div><div>1. Press STOP.</div><div>2. Repeat Temp Cal with fresh cuvettes.</div><div>3. If unable to correct the problem, call the Customer Support Center.</div></div>

TOO LITTLE RGT

Possible Cause	Corrective Action
<div><div>Wedge reagent pack empty.</div><div>Snap cap left on wedge reagent pack.</div><div>R-boom or Z-boom not properly positioned.</div><div>Probe failed to sense fluid properly.</div><div>Probe not attached in boom arm properly.</div></div>	<div><div>1. Press STOP.</div><div>2. Remove snap caps before initiating run.</div><div>3. Replace empty wedge reagent pack and repeat run.</div><div>4. Ensure that the probe is properly positioned by performing a reagent carousel calibration (Test 3.13).</div><div>5. If a problem occurs with the new wedge reagent pack, wash and dry the probe. Check the probe attachment. If the problem is not solved, replace the probe.</div><div>6. Perform Automated Probe Positioning and Boom Calibration (Test 3.10).</div><div>7. If unable to correct the problem, call the Customer Support Center.</div></div>

> = THRESHOLD

Possible Cause	Corrective Action
When running an abused drug assay with System 6.7 (T PRINT) set at 1, and the concentration is greater than or equal to the Threshold value specified in assay parameter .4 (THRSHLD).	No corrective action is required as this is a message signifying that the result is greater than or equal to the stored Threshold. This message will appear instead of the concentration and no NET P and BLK I values will print.



> = T

Possible Cause	Corrective Action
When running an abused drug assay with <b>System 6.7</b> (T PRINT) set at 0, and the concentration is greater than or equal to the Threshold value specified in assay parameter .4 (THRSHLD).	No corrective action is required as this is a message signifying that the result is greater than or equal to the stored Threshold. This message will appear after the concentration and the NET P and BLK I values will print.
***** PRINTED INSTEAD OF BLK I	

Possible Cause	Corrective Action
Extremely high Blank I reading.	<div><div>1. If isolated to one or a few samples, check to see whether patient(s) have been injected with a fluorescing compound for another diagnostic procedure.</div><div>2. Run <b>Photo Check (Test 2.2)</b>. Do any values fall out of specifications?<div>NO – Proceed to Step 3.</div><div>YES – Refer to “<b>Photo Check Out of Specifications</b>” under <b>Observed Problems</b>.</div></div><div>3. Run a different assay. Do BLK I values still print out all *****?<div>NO – Use new reagent pack for original assay.</div><div>YES – <div>1. Use a new container of buffer.</div><div>2. Call the <b>Customer Support Center</b> if problem continues.</div></div></div></div>

\*\*\*\*\* PRINTED INSTEAD OF I RESULT ON PIPET CHECK

Possible Cause	Corrective Action
	<div><div>1. Use a fresh bottle of Pipet Check Solution and repeat <b>Pipet Check</b>, ensuring that the cuvettes are clean and the Pipet Check Solution is carefully dispensed into the sample well of the sample cartridge.</div><div>2. Run <b>Photo Check</b>. Do any values fall out of specifications?<div><div>NO – Proceed.</div><div>YES – Refer to “<b>Photo Check Out of Specifications</b>” under <b>Observed Problems</b>.</div></div></div><div>3. Wash and dry the probe.</div><div>4. Perform a <b>buffer run</b> to observe the dispensing process. Check the probe’s positioning in the sample well if necessary.</div><div>5. Check the dispenser, probe and interconnect tubing for possible leaks. <b>Replace tubing</b> and <b>probe</b> if necessary.</div><div>6. Run an assay. Are the correct values printed?<div><div>YES – Use a fresh vial of Pipet Check solution and repeat <b>Pipet Check</b>.</div><div>NO – Call the <b>Customer Support Center</b>.</div></div></div><div>7. If unable to correct the problem, call the <b>Customer Support Center</b>.</div></div>

Air Bubbles in Dispenser	6-97
Barcode Scanner Not Responding	6-98
Boom Arm Strikes Reagent Vials	6-98
Boom Calibration (Test 3.2 or Test 3.10) Will Not Work Properly	6-99
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Display Blank	6-103
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NOVRAM Errors	6-106
Erratic Test Results	6-108
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Z-boom Calibration Not Working Properly	6-123



## AIR BUBBLES IN DISPENSER

## Corrective Action

1. Tap tubing during prime cycle to dislodge air bubbles.
2. Insert inlet tube all the way into buffer.
3. Straighten crimped tubing. **Replace tubing** if unable to straighten. Check all connections to be sure they are secure.
4. Tighten tubing connection at the valve block.
5. If air bubble is trapped on sample syringe plunger tip, run several prime cycles to dislodge the bubble. If this is not successful, **remove the syringe from the valve housing** (as described in **Section 5.0 Maintenance**), disassemble and clean the plunger with deionized water and a lint-free tissue. Reassemble the syringe and return it to the valve housing. Prime several times.
6. If air bubbles are trapped on the diluent syringe plunger tip, do the following:
  - a. Unscrew the buffer inlet tubing and remove the buffer bottle.
  - b. Move the boom arm to the center of the instrument by pulling on the boom-arm barcode reader assembly. Place a test tube or other receptacle under the probe.  
**CAUTION: Placing a test tube under the probe is necessary to prevent buffer spills inside the instrument.**
  - c. Unscrew the syringe retainer.
  - d. Push the plunger up and pull down rapidly to dislodge bubbles.
  - e. Remove and discard the test tube with buffer.
  - f. Reattach the syringe retainer to the drive block ensuring that the plunger is reseated properly.
  - g. Place the buffer container back in the instrument and reattach the inlet tubing.
  - h. Prime the system three times to dislodge bubbles. It may be necessary to repeat step (d) to completely dislodge bubbles.
  - i. If bubbles remain, remove and disassemble syringe.
  - j. Wipe plunger tip with a non-abrasive tissue or other suitable material. Wipe the inside of the glass barrel with a cotton swab.
  - k. Fill syringe with buffer or deionized water and tap gently to remove air bubbles.
  - l. Reattach diluent syringe.
  - m. Prime system three times.
7. Reseat valve block.
8. If bubbles continue to appear, **replace inlet tubing, diluent syringe, sample syringe or valve block.**

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**BARCODE SCANNER NOT RESPONDING**

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**Corrective Action**

1. Ensure the barcode scanner has been properly reconfigured.
2. Verify that the barcode scanner is properly connected to the barcode scanner port found on the TDxFLx<sup>®</sup> Analyzer back panel.
3. If the barcode scanner is faulty, use the numerical keypad for all necessary entries.
4. If unable to correct the problem, call the **Customer Support Center**.

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**BOOM ARM STRIKES REAGENT VIALS**

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**Corrective Action**

**CAUTION:** Check probe tip for possible damage after observing this problem. If damage is observed, **replace probe**.

1. Check reagent pack to be sure it is properly positioned and vial and snap caps have been removed. Reseat reagent pack if necessary.
2. Check the **batch-pack adapter** and ensure that it is installed properly.
3. Push reagent vials down into reagent pack to be sure they are fully seated.
4. Ensure that the batch reagent pack is seated properly in the **batch-pack adapter**.
5. Disable door lock sensor (**System 2.2** = 0) and observe a **buffer run**.

If the probe strikes the edge of the vial as the boom moves vertically, the R-boom position step numbers may not be correct. Perform **Automated Probe Positioning and Boom Calibration (Test 3.10)** and **Reagent Carousel Calibration (Test 3.13)**.

If the probe strikes the vial as the boom moves horizontally, check the length of the probe tubing to ensure it is sufficient and is not hindering the movement of the boom arm.

Perform a **Z-boom Calibration (Test 3.5)** to ensure the proper height of the boom arm. Check that the probe is inserted all the way up into the boom arm.

6. Enable door lock sensor (**System 2.2** = 1).
7. If unable to correct the problem, call the **Customer Support Center** with all information.

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**BOOM CALIBRATION (TEST 3.2 or TEST 3.10) WILL NOT WORK PROPERLY**

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**Corrective Action**

1. **Print Test 3.2.** Check the parameters printed with the values given below. If the values stored in the memory of the instrument are not within  $\pm 2$  steps, edit them accordingly.

These parameters determine where the barcode reader will begin to look for the carousel label.

3.2.5 CAR STR 260

3.2.6 CAR STC 1661

2. When the values have been edited and stored, repeat the **Boom Calibration**.

**NOTE:** When Boom Cal is repeated, the probe positions will not be correct. Every time this test is run, the instrument uses default values to position the probe. These values are not the probe positions previously stored in Boom Cal.

3. Ensure the calibration (CAL) carousel is being used. If necessary, relabel the carousel.
4. Ensure that the new **System 3** parameters that have been defined are stored with the STORE key before exiting **Test 3.2**. To check the parameters after they are stored, perform a **buffer run**.
5. If unable to correct the problem, call the **Customer Support Center**.

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**CALIBRATION CURVES NOT STABLE FOR 14 DAYS - QC OUT OF RANGE**

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**Corrective Action**

1. Are all levels of TDxFLx<sup>®</sup> System controls outside the ranges stated in the assay manual insert for the specific reagent system in question?  
YES – Proceed to step #2.  
NO – Use a new vial of the control whose value is outside the accepted range. If the value for the new vial of control is within range, there is no problem with the calibration curve stored in memory. If the value is still outside the range, proceed to step #2.
2. Are all reagent systems exhibiting the problem?  
YES –
  - a. To determine whether the instrument is functioning properly, run a **Photo Check (Test 2.2)**, a **Pipet Check (Test 2.3)** and a **Temperature Check (Test 2.1)**. Analyze the results of each check and take the appropriate corrective action if any results are not within specifications. If all results are within specifications, proceed to (b).
  - b. If the buffer container has been changed, all assays may need to be recalibrated.
  - c. Check the probe's positioning in the predilution well to ensure proper mixing using **Probe-Positioning Check and Adjustment procedure**.
  - d. Replace the dispenser components; **probe**, **sample syringe**, **diluent syringe**, and **valve**. Ensure the inlet tubing and interconnect tubing are not crimped. If a crimp is found, **reposition or replace the tube**. Refer to **Section 5.0 Maintenance**.
  - e. If the problem recurs frequently, call the **Customer Support Center**.  
NO – Proceed to step #3.
3. Does the calibration curve instability occur only with an assay requiring a sample preparation step?  
YES –
  - a. Check the accuracy and reproducibility of the pipettors used to dispense the appropriate sample preparation reagent and the samples.
  - b. Ensure the sample preparation reagent is dispensed into the centrifuge tubes before the sample is added (except for the Total T<sub>3</sub> PLUS assay).
  - c. Ensure the sample preparation reagent and sample are thoroughly vortexed before centrifugation.
  - d. Ensure the sample preparation reagent has not expired.
  - e. If centrifugation is necessary, **check the centrifuge RPM. Calibrate the centrifuge** if necessary.
  - f. Recalibrate using a new package of calibrators and controls.
  - g. Remove batch reagent pack or reagent carousel from instrument promptly after assay completion. Recap vials and store properly.  
NO – Proceed to step #4.



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**CALIBRATION CURVES NOT STABLE FOR 14 DAYS - QC OUT OF RANGE** (continued)

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**Corrective Action**

4. Open a new batch or wedge reagent pack and run all levels of TDxFLx<sup>®</sup> System controls. Are the controls within range when the new reagent pack is used?

YES – The reagent pack which exhibited the problem was subjected to some trauma. The following items could cause this problem:

- a. Leaving the opened reagent pack in the instrument will cause evaporation.
- b. Putting the reagent vial caps on the wrong vials will contaminate the reagents. Putting the snap caps on the wrong wedge pack will also contaminate the reagents.
- c. Spilling any solution into the vials will cause contamination of the reagents.
- d. Improper storage of reagent pack.

NO – If any of the changes listed below have been made since the last calibration, the change could be the cause of the calibration curve change. Recalibrate the reagent system, note the date of calibration in the maintenance log and monitor the stability of the new calibration curve.

- new lot number of reagent
- new lot number of buffer
- **replacement of a dispenser component**
- performance of any instrument calibration procedure (**Diagnostic Test 3**).

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**CALIBRATION FAILS TO MEET SPECIFICATIONS**


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**Corrective Action**

PERR or ERR too large  
RMSE too large

1. RMSE and PERR or ERR specifications are to be used only as guidelines. If controls are in range, proceed with reporting patient results.
2. If controls are outside the specified range, was the run terminated during the processing of the curve by pressing **STOP** or opening the door and a reprint of the data obtained?  
 NO – Proceed to step 3.  
 YES – Repeat the run.
3. If all controls are outside the specified range, wash and dry the probe. Set up a new calibration carousel assuring there are no air bubbles in the samples or in the dispenser tubing. Ensure that reagents, calibrators and controls are mixed prior to use.
4. Does problem occur with more than one assay?  
 NO – a. Check the calibrator concentration values to be sure they are programmed correctly. Refer to the assay manual insert.  
       b. Replace reagent pack, calibrators and **buffer**. Repeat calibration after replacing each item to isolate cause of problem.  
       c. If unable to correct the problem, call the **Customer Support Center**.  
 YES – Proceed to step 5.
5. If this problem occurs in the batch mode, observe a **Dispense Check (Test 6.3)** to verify probe performance. If the problem occurs in the random access mode, perform a random access **buffer run** to verify probe performance.
6. Run **Photo Check (Test 2.2)**. Does it pass specifications?  
 NO – Refer to “**Photo Check out of specifications**”.  
 YES – Proceed.
7. Run **Pipet Check (Test 2.3)**. Does it pass specifications?  
 NO – a. Replace dispenser components in the order indicated (Refer to Section 5.0 Maintenance). Repeat **Pipet Check** after replacing each item.  
       1 – probe  
       2 – sample syringe  
       3 – diluent syringe  
       4 – valve  
       b. If unable to correct the problem, call the **Customer Support Center**.  
 YES – Proceed to **step 8**.

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**CALIBRATION FAILS TO MEET SPECIFICATIONS** (continued)

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**Corrective Action**

8. Run **Temperature Check (Test 2.1)**. Does it meet specifications?  
NO – Refer to **Temp Check out of specification**.  
YES – Proceed to step 9.
9. **Replace buffer container**.
10. Use new reagent pack and calibrators.
11. If unable to correct the problem, call the **Customer Support Center**.

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**DISPLAY BLANK**

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**Corrective Action**

1. Turn the power switch, located in the rear of the instrument, off.
2. Reseat the power cord on the TDxFLx<sup>®</sup> Analyzer and in the outlet.
3. Turn the rear panel power switch on.
4. Does system status display read [DATE \_\_ \_\_ . \_\_ \_\_ . \_\_ \_\_] ?  
NO –
  - a. Check outlet to be sure it has proper power.
  - b. Check that rear panel was installed properly with interlock switch covered.
  - c. If unable to resolve problem, make a note whether printer responds (by advancing platen) when power switch is turned on and call the **Customer Support Center**. If a letter or symbol appears in right-hand side of display, refer to **DISPLAY SHOWS SINGLE CHARACTER** under **Observed Problems**.  
YES – Proceed to step 5.
5. Enter and store the correct date and time. When the display shows [READY], unit is ready for operation. Calibration curves previously run will still be stored in memory.

DISPLAY SHOWS “READY    S=XX%”

Possible Cause

This message implies that the bilateral communication between the instrument and the computer may not be working properly. Data will be stored in NOVRAM memory and will not be lost until the display shows:



Once this happens, storage space has been filled up; therefore, earliest data will be overwritten and lost unless communication systems are reestablished.

**CAUTION: DO NOT run any further assays once the spooler is full. Doing so will cause data to be lost.**

For this function to be active, the following parameters need to be verified:

- SYSTEM 2.9 - STORAGE

Should be set to 1  
Press **SYSTEM 2.9 EDIT 1 STORE STOP**.
- SYSTEM 2.4 - BAUD

Should be set to the same value as the baud rate of computer collecting the data. This parameter is factory set to 4800 in the TDxFLx<sup>®</sup> Analyzer. Available baud rates are 110, 300, 600, 1200, 2400, and 4800.

Corrective Action

1. If bilateral communication function is used, continue with Step 2. If bidirectional communication function is not desired, set STORAGE parameter to 0. Press **SYSTEM 2.9 EDIT 0 STORE STOP**. To erase unwanted data already stored in memory and to update the display, press **TEST 3.12 RUN** - Reset pointers. The display should read [READY].
2. Check to verify that RS232 cable is properly attached to the RS232 port found in the back panel.
3. Ensure that the TDxFLx<sup>®</sup> System baud rate and computer baud rate are the same. If not, edit the value making sure the rate is one of those numbers above.
4. Verify that the computer’s data collection program is functioning properly.
5. If unable to correct the problem, call the **Customer Support Center**.

DISPLAY SHOWS SINGLE CHARACTER

Character Displayed	Possible Cause
1, 2, 3, 4, 5, 6, 7, 8 or 9 < or > on power up : or ; < or > during edit	Memory failure (Circuit Board #2). Attempting to enter an unacceptably small ( < ) or large ( > ) number.
	<b>Corrective Action</b>  If < or > shows in the display while a parameter is being edited, the value which has been entered is not acceptable. Press <b>STOP</b> and reenter the correct acceptable volume.  If any character shows in the display either during the power up sequence, while the instrument is at [READY] or during normal operation of the instrument, refer to the instructions below.  <ol style="list-style-type: none"><li>1. If any of the characters listed above show in the right-hand side of the display, turn the instrument off and wait 30 seconds.</li><li>2. Turn power on and initialize system.</li><li>3. If problem recurs, turn instrument off and unplug it.</li><li>4. Remove rear panel.</li><li>5. Remove the appropriate printed circuit boards (PCBs) one at a time. Clean PCB contacts with methanol on a wipe and reseal board. Ensure the components are facing toward the right and the board is aligned on the upper and lower guide rails. Ensure each PCB “clicks” into position when reseated. A significant amount of force is required to do this.</li><li>6. Replace rear panel.</li><li>7. Plug instrument in and turn power on. Initialize system.</li><li>8. If problem recurs, call the <b>Customer Support Center</b> with all information.</li></ol>

NOVRAM ERRORS

Corrective Action

The possible cause for this failure depends on the operation being performed when the error occurred. Refer to the list below to determine the possible cause and corrective action which should be taken. Note that some conditions only display a message while others will both display and print a message. If unable to correct the problem, call the **Customer Support Center**.

Condition	Possible Cause	Corrective Action
BOOM CALIBRATION being run.	Unable to store parameter in memory.	<div><div>1. Press <b>STOP</b>.</div><div>2. Repeat <b>Boom Calibration</b> (<b>Test 3.2</b> or <b>Test 3.10</b>).</div></div>
Calibration run (Displays and prints NOVRAM ERROR - CRV FIT).	Calibration curve data not stored correctly.	<div><div>1. Press <b>STOP</b>.</div><div>2. Repeat calibration with fresh calibrator samples.</div></div>
Power up sequence (initialization).	Memory failure. (Circuit Board #2)	<div><div>1. Turn power off and wait 30 seconds.</div><div>2. Turn power on and initialize system.</div><div>3. If problem recurs, turn power off and unplug instrument.</div><div>4. Remove rear panel.</div><div>5. Remove PCB # 2, clean board contacts with methanol on a non-abrasive tissue, and reseal board into card cage.</div><div>6. Replace rear panel.</div><div>7. Plug instrument in and turn power on. Initialize system.</div></div>

NOVRAM ERRORS (continued)

Condition	Possible Cause	Corrective Action
PHOTO CALIBRATION being run (Displays and prints error message).	Unable to store parameter in memory.	<div><div>1. Press <b>STOP</b>.</div><div>2. Print parameters for <b>Test 3.4</b> and verify gain, intensity and polarization value are the same as those values on the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label.</div><div>3. Edit any parameters which do not match so the instrument parameters are the same as the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label.</div><div>4. Rerun <b>Photo Calibration (Test 3.4)</b>.</div></div>
Self-diagnostic check after first test of the day (displays and prints NOVRAM ERROR-DAILY CHECK).	Self-diagnostic check run failed.	Call the <b>Customer Support Center</b> .
TEMPERATURE CALIBRATION being run.	Unable to store parameter in memory.	<div><div>1. Press <b>STOP</b>.</div><div>2. Repeat <b>Temperature Calibration (Test 3.1)</b>. Assure correct temperature value is entered.</div></div>
PIPET CHECK.	Unable to set MN TR (assay parameter .21) in assays.	Call the <b>Customer Support Center</b> .

## ERRATIC TEST RESULTS

**Corrective Action**

Review the following items and take corrective action as appropriate. Refer to **Section 5.0** Maintenance if component replacement is needed.

1. Cuvette upside down.
2. Disposable component was not clean, or foreign matter was present.
3. No calibration curve in memory. (Check date on header, if no calibration curve has been stored, calibration date will be 00/00/00.)
4. Air bubbles in sample wells or reagent vials.
5. Sample splashed into predilution chamber.
6. Air bubbles in tubing or syringes.
7. Syringes slipping or leaking. Syringe retainer loose.
8. Probe dirty or damaged. Wash and dry probe or **replace**.
9. Tubing loose on liquid heater connector.
10. Carousel dirty.
11. Probe bent or squeezed causing improper mixing or possible carryover.
12. Probe not properly positioned over predilution well causing improper mixing. If running in the batch mode, run a **Dispense Check (Test 6.3)** and observe probe performance in the predilution well. Change the probe if necessary. If running in the random access mode, perform a **buffer run (Test 3.14)**.
13. Probe not properly positioned over predilution or sample wells, causing improper sampling. Refer to **Probe-Positioning Check and Adjustment** using probe-positioning cartridge.
14. Valve leaking; reseal or **replace valve block**.
15. Locking tabs broken on sample carousel. This prevents the cuvettes from being held stationary during the run. Discard carousel and order a new one.
16. Photomultiplier tube (PMT) fatigue due to access door being left open. Run a **Photo Check (Test 2.2)**.
17. The door was opened, with **System 2.2** disabled, during the run.
18. To determine whether the instrument is functioning properly, run a **Photo Check (Test 2.2)**, a **Pipet Check (Test 2.3)** and a **Temperature Check (Test 2.1)**. Analyze the results of each check and take the appropriate corrective action if any results are not within specification.
19. If unable to correct the problem, call the **Customer Support Center**.



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**FREQUENT DISPLAY OF AIR, OPT OR LIQ TEMPERATURE**

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**Corrective Action**

1. If “AIR or LIQ or OPT T” = 0.0, call the **Customer Support Center**.
2. Check cooling fan inlet, located in the center of the underside of the TDxFLx<sup>®</sup> Analyzer, for partial obstruction. Remove any obstruction found. Refer to the **air-fan filter cleaning procedure** in the **Maintenance section**.
3. Ensure that there is at least a 6” clearance on all sides of the system.
4. Access door left open. Keep door closed at all times when not inserting reagents or carousel.
5. Be sure room temperature is within the specifications.
6. Be sure instrument is not in direct sunlight or draft from fan or air duct.
7. Run **Temperature Check (Test 2.1)** and check results against specifications.
8. If LIQ temperature is too high, prime two or three times.
9. If problem persists, call the **Customer Support Center**.

## HIGH TEST RESULTS

## Corrective Action

1. Are most samples affected?

NO – a. Repeat sample (use **Dilution Protocol** if “HI” printed instead of concentration.)

**CAUTION: The Dilution Protocol procedure is only available for some assays. Refer to the appropriate assay manual insert to determine the dilution procedures for specific assays.**

b. If value does not correlate with original result, proceed to step 2.

YES – Proceed to step 2.

2. Review the following items and take corrective action as appropriate. Refer to **Section 5.0** Maintenance if component replacement is needed.
  - a. Serum accidentally dispensed or splashed into cuvette or predilution chamber in sample cartridges.
  - b. Assay parameters not correct. Verify that assay parameters match values listed in the assay manual insert or kit enclosure.
  - c. Carryover on probe. Wash and dry probe. **Replace probe** if problem still exists.
  - d. Air bubbles in tubing or syringes. Remove or **replace tubing** as needed.
  - e. Slipping or leaking diluent syringe. Reseat or **replace** as needed.
  - f. Inlet tube not fully seated into buffer container.
  - g. Leaking valve. Reseat or **replace valve block** and repeat run.
  - h. Perform the **Probe-Positioning Check and Adjustment procedure**.
  - i. Controls out of range. Recalibrate assay and rerun.
3. If unable to correct the problem, call the **Customer Support Center** with all information.

## LOW TEST RESULTS

**Corrective Action**

1. Check for bubbles in sample well.
2. Verify that assay parameters match values listed in the assay manual insert or kit enclosure.
3. Probe height not properly adjusted. Refer to **Z-boom Calibration (Test 3.5)**.
4. If using the **Barcode Override procedure**, ensure the batch reagent pack being used corresponds to the assay number used in the **barcode override**.
5. During a random access run, ensure that the assay specified for the sample is correct when you enter the sample load list during a random access run.
6. Press **PRIME** and observe dispenser for possible leaks, air bubbles or slipping syringes. Correct problem as applicable.
7. Ensure proper probe positioning in sample well and predilution well by observing a **Dispense Check (Test 6.3)**. If necessary, perform a **Probe-Positioning Check and Adjustment procedure** using probe-positioning cartridge. If the problem occurs with random access assays, perform a random access **buffer run (Test 3.14)** and a **Reagent Carousel Calibration (Test 3.13)**, if necessary.
8. If problem still occurs, change the probe.
9. If controls are out of range, recalibrate assay.
10. Reagent vials out of order in reagent pack. Repeat assay using a new reagent pack.
11. Repeat assay using a new buffer container.
12. If unable to correct the problem, call the **Customer Support Center**.

---

**NO RESULTS PRINTED**

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**Impact Printer****Corrective Action**

If the date, time and assay name were not printed –

1. Attempt to redisplay and reprint data using **System 4.1 and 4.2**, respectively.

2. Turn TDxFLx<sup>®</sup> System power off.

**NOTE:** All results are deleted when the system is powered off.

3. Ensure printer ribbon is threaded properly.

4. Move printhead to the center of the guide shaft.

5. Turn the TDxFLx<sup>®</sup> System power on. Verify that the printer returned to its left-hand home position. Repeat run after initializing TDxFLx<sup>®</sup> Analyzer.

6. If problem recurs, clean and lubricate the printer.

7. If unable to correct the problem, call the **Customer Support Center**.

**Thermal Printer****Corrective Action**

1. Ensure that the correct thermal paper is being used (Abbott LN 9684-07).

2. Ensure that the thermal paper is feeding properly from the underside of the roll through the thermal printer paper guides.

3. Ensure that the printer head release lever is pushed towards the back of the printer (engaged/vertical position).

4. Attempt to reprint and redisplay data using **System 4.1 and 4.2** respectively.

5. Turn the TDxFLx<sup>®</sup> System power off.

**NOTE:** All results are deleted when the system is powered off.

6. Turn the TDxFLx<sup>®</sup> System power on. Repeat run after initializing the system.

7. If unable to correct the problem, call the **Customer Support Center**.

## NOISE COMING FROM ANALYZER

## Corrective Action

1. Did noise occur during operation?  
NO –
  - a. Check cooling fan intake under the center of the instrument for obstruction. Remove obstruction. **Clean the air-fan filter** if necessary.
  - b. Attempt to run an assay. If results are within control ranges, proceed with assays and notify the **Customer Support Center**.
  - c. If unable to operate instrument, call the **Customer Support Center**.  
YES – Proceed to step 2.
2. Press **STOP**.
3. Open access door and check following items. Take corrective action as appropriate.
  - a. Reagent vial caps not removed.  
Reagent snap caps not removed.
  - b. Batch reagent pack not seated properly.  
**Batch-pack adapter** improperly installed.
  - c. Reagent vial not fully pushed down in reagent pack.
  - d. Sample carousel not properly seated.  
Reagent carousel improperly seated.
  - e. Vial cap liner stuck on top of vial.
  - f. Observe boom arm movement (remember to disable door lock by editing **System 2.2** to 0 to make it possible to watch operation).
  - g. Ensure that the probe tubing length is sufficient so it does not hinder the boom arm movement.
  - h. Ensure liquid-level-sensing electrodes are properly attached in the end of the boom arm.  
Ensure the thumbscrew is tight.
  - i. Enable door lock (**System 2.2** = 1).
4. Lift buffer door and check syringes for breakage.
5. Press **PRIME** and observe syringe operation. Take corrective action as necessary.
6. If beeper is stuck, turn TDxFLx<sup>®</sup> Analyzer power off. Wait a few seconds, then turn TDxFLx<sup>®</sup> Analyzer power on and initialize system. If necessary, edit **System 2.1** to 0 to turn the beeper off.
7. If beeper is periodically activated, ensure the access door is kept closed when at [READY].  
Ensure the batch reagent pack, the reagent carousel, and the sample carousel have been removed at the completion of the run.
8. If unable to correct the problem, call the **Customer Support Center**.

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**PAPER JAMS OR FAILS TO ADVANCE**

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**Impact Printer****Corrective Action**

1. Re-thread paper onto printer platen ensuring it feeds straight.
2. Adjust black paper guides on bar behind platen so paper is guided properly. Guides should be just touching the paper edges.
3. If paper is sticking to printer cover, lift cover and spray cover with an antistatic spray.
4. Check paper roll to be sure it is not binding inside printer. Using slight pressure, spread open the metal plates which hold the spindle, to avoid binding the paper.
5. **Replace paper roll**, ensuring that the paper feeds from the underside of the roll.
6. Check to be sure correct paper is used. If paper is too smooth, it will slip on the platen instead of advancing. Order paper from Abbott (LN 9520-20).
7. Clean the platen with isopropanol.
8. Clean and lubricate printer.
9. If printhead is catching on paper, use a blade screwdriver to gently bend the brass foot on the printhead a little away from the paper.

**Thermal Printer****Corrective Action**

**NOTE:** If a run is in progress, allow the run to go to completion before taking corrective action.

1. Ensure that the printer head release lever is pushed towards the back of the printer (engaged/vertical position).
2. Ensure that the thermal paper is feeding properly from the underside of the roll through the thermal printer paper guides.
3. Ensure that sufficient paper has fed through the paper exit slot.
4. Ensure that paper roll is not binding inside printer.
5. Ensure that the correct thermal paper is being used (Abbott LN 9684-07).
6. If unable to correct the problem, call the **Customer Support Center**.

## PHOTO CHECK OUT OF SPECIFICATIONS

## Corrective Action

1. a. When TDxFLx<sup>®</sup> Analyzer display shows [READY] press **TEST 2.2.1 DISPLAY**. If the gain value showing in the display is not the same as the gain on the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel label, edit the displayed value to agree with the label.
- b. Check the gain, intensity and polarization in **Test 3.4**. If they do not match the label on the X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel, edit the **Test 3.4** values to agree with the label.
- c. Ensure that the same X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel is used for the **Photo Check procedure** that was used for the **Photo Calibration procedure**. X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel(s) may be labeled with the applicable TDxFLx<sup>®</sup> Analyzer serial number(s) by placing a label on the inner ring opposite the factory-installed carousel label.
- d. Repeat **Photo Check (Test 2.2)**.
2. Has X SYSTEMS<sup>®</sup> Fluorometric Standards Function Test Set Carousel been left outside of the storage box?
  - NO – Proceed to step 3.
  - YES – a. Place in storage box for one hour.
  - b. Rerun **Photo Check**.
  - c. If still out of specifications, proceed.
3. Clean all ampules with lens paper, then rerun **Photo Check**.
4. Clean aperture located on the inside left wall of the lamp housing.
5. Check optics lenses to see if they have slipped out of place.
6. Ensure no air bubbles are trapped in lower portion of ampules. Invert carousel several times to dislodge bubbles if necessary.
7. If the polarization range is greater than 2.5 mP, run a CV Check. Are results within acceptable limits?
  - NO – Proceed to step 8.
  - YES – a. Rerun **Photo Check**.
  - b. If results are still out of specifications, call the **Customer Support Center**. Proceed with assay runs being sure to verify all control results.
8. **Replace the lamp**. Refer to **Section 5.0 Maintenance**.
9. Perform **Photo Calibration (Test 3.4)**. Recalibration of all assays may be necessary after running a Photo Calibration running patient samples. Verify control results before running patients. Recalibrate assays where controls are not within acceptable range.
10. If unable to correct the problem, call the **Customer Support Center**.

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## PIPET CHECK OUT OF SPECIFICATIONS

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### Corrective Action

If an error message printed, refer to Printed Error Codes “**AVG I TOO SMALL**” and “**AVG I TOO LARGE**” or “**FAILED - RNG I OUT OF SPEC**” for Pipet Check. Refer to **Section 5.0 Maintenance** if component replacement is needed.

1. Check for upside-down cuvette, and repeat **Pipet Check (Test 2.3)**.
2. Check for leaks or crimps in tubing. Secure tubing connections or **replace tubing** as necessary. Repeat **Pipet Check**.
3. Check for air bubbles in sample wells. Repeat **Pipet Check**.
4. Wash and dry probe. Inspect for damage or wear. **Replace**, if necessary. Repeat **Pipet Check**.
5. Wash any buffer residue on carousel, and repeat **Pipet Check**.
6. **Replace probe**, and repeat **Pipet Check**.
7. Perform the following procedures after replacing probe:
  - a. **Automated Probe Positioning and Boom Calibration (Test 3.10)**.
  - b. 4-pot **Boom Calibration (Test 3.7)**, if applicable.
  - c. **Unit Dose Boom Calibration (Test 3.6)**, if applicable.
8. **Replace sample syringe**, and repeat **Pipet Check**.
9. **Replace diluent syringe**, and repeat **Pipet Check**.
10. **Replace valve block**, and repeat **Pipet Check**.
11. Recalibration of assays may be necessary after replacing **probe**, **syringe**, or **valve block**. Check to ensure that controls are in range.
12. If unable to correct the problem, call the **Customer Support Center**.



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**PRIME DOES NOT OPERATE**

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**Corrective Action**

1. Does display show [READY]?
  - NO – a. If an error message is displayed, refer to appropriate displayed message in this section.
  - b. If [DATE \_\_\_\_ . \_\_\_\_ . \_\_\_\_] appears in the display, enter and store date and time. When [READY] is displayed, proceed to step 2.
  - YES – Proceed.
2. Press **STOP** and **PRIME**. Do diluent and sample syringe drive blocks move down?
  - NO – a. Press **PRIME** again to assure it was actuated. Verify that **System 2.1** is set to 1. Listen for “beep” to assure button was actuated.
  - b. Turn power off then on and re-initialize the instrument by entering and storing the correct date and time.
  - c. If instrument still fails to prime, call the **Customer Support Center**.
  - YES – If buffer is being dispensed through the probe, perform an assay run. If no buffer is dispensed, proceed to step 3.
3. Was valve block just installed?
  - NO – a. Be sure inlet tube is seated all the way down into buffer container.
  - b. Check container to be sure there is sufficient buffer (buffer platform may be mispositioned).
  - c. Reseat or **replace inlet tube** from valve to buffer.
  - d. Reseat or **replace valve block**.
  - e. Reseat or **replace interconnect tubing**.
  - f. If unable to correct the problem, call the **Customer Support Center**.
  - YES – Remove valve housing and reseal. Follow **Valve Block Replacement procedure**. (It may be necessary to rotate the extender shaft 180° and reinstall the valve two or three times if the valve core needs realignment).

---

**PRINTER DOES NOT PRINT**

---

**Impact Printer****Corrective Action**

1. Lift printer door. Grasp printhead and move it back and forth on guideshaft. Does it move smoothly?  
NO – Clean and lubricate printer.  
YES – Proceed to step 2.
2. **Replace ribbon** and check printer operation by using **Test 5.4.1**.
3. Power TDxFLx<sup>®</sup> System off and on. Verify that the printer line feeds and the platen turns.
4. If unable to correct the problem, call the **Customer Support Center**.

**Thermal Printer****Corrective Action**

1. Ensure that the correct thermal paper is being used (Abbott LN 9684-07).
2. Ensure that the thermal paper is feeding properly from the underside of the roll through the thermal printer paper guides.
3. Ensure that the printer head release lever is pushed towards the back of the printer (engaged/vertical position).
4. Attempt to reprint and redisplay data using **System 4.1 and 4.2** respectively.
5. Turn the TDxFLx<sup>®</sup> System power off.  
**NOTE:** All results are deleted when the system is powered off.
6. Turn the TDxFLx<sup>®</sup> System power on. Repeat run after initializing the system.
7. If unable to correct the problem, call the **Customer Support Center**.

---

**PRINthead JAMS**

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**Impact Printer****Corrective Action**

1. Clean and lubricate printer.
2. Reposition ribbon on guides ensuring the ribbon is on top of movable brass guide attached to the printhead.
3. If one ribbon spool is near the end, make sure it is rewinding properly. If not rewinding properly, move gray ribbon reverse bar to opposite position on printhead. If problem recurs, call the **Customer Support Center**.
4. Adjust black paper guides on bar behind platen so paper is guided properly. The guides should be just touching the edges of the paper.
5. If printhead is catching on paper, use a blade screwdriver to gently bend the brass foot on the print-head a little away from the paper.
6. If unable to correct the problem, call the **Customer Support Center**.

---

**PRINTOUT SQUEEZED TOGETHER**

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**Impact Printer****Corrective Action**

1. Clean and lubricate printer.
2. Reposition ribbon on guides ensuring the ribbon is on top of movable brass guide attached to the printhead.
3. If unable to correct the problem, call the **Customer Support Center**.

**Thermal Printer****Corrective Action**

1. Press the **PRINT** key several times to advance the paper. Do not pull the thermal paper through the printer.
2. If unable to correct the problem, call the **Customer Support Center**.

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**RAPID SYRINGE WEAR**

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**Corrective Action**

1. Remove the syringe(s) from the valve block according to the **Syringe Replacement procedure** in **Section 5.0 Maintenance**.
2. Reattach carefully to avoid cross threading.  
It may be necessary to turn the syringe 180° when reattaching it so the syringe seats easily into the detent on top of the drive block.
3. Reattach the syringe clamp or retainer, ensuring that the plunger is seated securely in the detent on the driver block.
4. If problem continues, **replace valve block**. Refer to **Section 5.0 Maintenance**.
5. If problem continues, call the **Customer Support Center**.

---

**REAGENT DISPLAY DOES NOT LIGHT UP ASSAY NAMES AFTER INITIATING RUN**

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**Corrective Action**

The possible cause(s) for this failure may be due to one, several, or a combination of system components. The first step to take in order to solve this problem is to call the **Customer Support Center**. The operator, however, is able to continue using the instrument, if desired, by performing the following steps until the problem is resolved.

1. Insert the reagent carousel and the sample carousel into the system. Press **RUN** and determine if the reagent carousel barcode reader is functioning correctly.
  - a. If the reagent carousel barcode reader is functioning correctly, assay names should be displayed on the main display. The list of reagents should also be printed. Continue with Step 2.
  - b. If the reagent carousel barcode reader is not functioning correctly, assay names should not be displayed on the main display. The list of reagents printed should be blank. Continue with Step 3.
2. Follow the steps described in the **random access run procedure** of this manual (**Section 3.0**). When it is time to enter the sample load list, use the numerical keypad, instead of the reagent keypad, to enter the two-digit assay numbers for every sample on the carousel. Continue with Step 4.
3. Press **STOP**. Follow the steps described in the **random access barcode override procedure** of this manual (**Section 3.0**). When it is time to enter the sample load list, use the numerical keypad, instead of the reagent keypad, to enter the two-digit assay numbers for every sample on the carousel.
4. Be sure to save data tapes for future reference on the number of tests left on each wedge reagent pack until the problem has been corrected.
5. If unable to correct the problem, call the **Customer Support Center**.

## SAMPLE SKIPPED

**Corrective Action**

1. Ensure the correct volume of sample has been placed into the sample well.
2. Ensure the probe connector on the boom arm is clean and properly secured. Both overtightening and undertightening of the thumbscrew securing the probe can cause fluid-sensing failures.
3. Wash and dry the probe.
4. Run **Automated Probe Positioning and Boom Calibration (Test 3.10)**. Ensure the probe is in the center (from left to right and front to back) of the sample well by observing a **Dispense Check (Test 6.3)**. If the problem occurs in the random access mode, perform a random access **buffer run (Test 3.14)**.
5. Remove the probe and flush the end of the boom arm with deionized water. Thoroughly dry the spaces in the boom arm and reattach the probe.
6. If unable to correct the problem, **replace the probe**. Refer to **Section 5.0 Maintenance**.
7. If unable to correct the problem, call the **Customer Support Center**.

**SPLASHING OR FOAMING IN PREDILUTION WELL DURING DISPENSING****Corrective Action**

1. Follow the inspection procedure for the probe to determine the condition of the **probe**. If it is damaged, replace it. Refer to **Section 5.0 Maintenance**.
2. If the probe is not damaged, check the probe positioning over the predilution well by performing the **Probe-Positioning Check and Adjustment procedure**.
3. If unable to correct the problem, call the **Customer Support Center**.

**TEMPERATURE CHECK OUT OF SPECIFICATION****Corrective Action**

1. Check cuvettes to be sure they are all right side up.
2. Repeat **Temperature Check (Test 2.1)**.
3. If Temperature Check is still out of specification, call the **Customer Support Center**.

---

**TEST (ASSAY) DOES NOT START AFTER RUN**

---

**Corrective Action**

1. Does display show [READY]?

NO – Proceed to step 2.

YES – Press **RUN** carefully, being sure you can feel the button move slightly. With **System 2.1** memory set to 1, listen for “beep” to assure button was actuated. If problem still exists, proceed.

2. Can you hear the carousel revolving?

NO – a. Press **STOP** then press **RUN** ensuring you can feel the button move slightly.

b. If assay still does not start, turn power off then on again and initialize system. Run assay again.

c. If problem continues, call the **Customer Support Center**.

YES – Proceed to step 3.

3. Does the assay name appear in the display?

NO – a. Wait five (5) minutes.

b. If message appears in display refer to appropriate page in **Troubleshooting Section**.

c. If assay does not proceed normally, press **STOP** and call the **Customer Support Center**.

YES – a. Normal operation. Wait for assay to be completed.

b. If assay does not proceed normally, press **STOP** and call the **Customer Support Center**.

---

**Z-BOOM CALIBRATION NOT WORKING PROPERLY**

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**Corrective Action**

Review the four problems listed below (A, B, C or D); find the one which most nearly describes the problem you are experiencing. Take the corrective action as listed.

A. More than a 1 step spread in step # in the five positions.

This may be caused by one of two items, either the volume of buffer in the sample wells is not exactly 50  $\mu\text{L}$ , or the sample cartridge ring on the carousel has been broken or is warped. To isolate the cause of the problem, proceed as follows:

1. Switch the sample cartridges that are reading incorrectly to a position that is reading correctly.
2. Reread the step number where fluid is being detected by pressing **NEXT**.
3. If the incorrect reading stays with the sample cartridge moved to the new carousel position, the amount of buffer in the sample well is not correct. Accurately pipette 50  $\mu\text{L}$  of X SYSTEMS<sup>®</sup> Dilution Buffer into five clean sample cartridges and repeat the **Z-boom Calibration**.
4. If the incorrect reading stays with the carousel position, the sample cartridge ring on the carousel is broken or warped. Order a new carousel. Use another carousel to repeat the **Z-boom Calibration**. The defective carousel may be used for assays by adding extra sample to the sample well until the replacement is received.

B. Sample Missing

1. The solution in the sample well must be buffer or some other solution that will be conductive. Distilled or deionized water will not be detected.
2. Wash and carefully dry the probe and repeat the test. Verify probe attachment on the boom arm is correct. Ensure the thumbscrew is tight.
3. Watch where the probe is positioned as it goes into the sample well. Ensure the probe is centered in the well. If it is not positioned properly, edit **System 3.3** as needed to center the probe (Refer to **Probe-Positioning Check and Adjustment** procedure for sample well using the probe-positioning cartridge or perform an **Automated Probe Positioning and Boom Calibration (Test 3.10)**).
4. Ensure the 50  $\mu\text{L}$  of buffer is pipetted accurately.
5. Check the liquid-level sensing of the probe using **Test 4.4**.
6. If unable to correct the problem, call the **Customer Support Center**.

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**Z-BOOM CALIBRATION NOT WORKING PROPERLY** (continued)

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**Corrective Action**

C. Check the accuracy of the fluid volume used when **Z-boom Cal** was performed.

If a large volume of sample, greater than 100  $\mu\text{L}$ , was dispensed, the Z-boom HM selected by the TDxFLx<sup>®</sup> Analyzer may be an invalid number (greater than 252). **System 3.14** will then need to be edited to the last correct Z-boom HM step number. Repipette the samples and repeat **Z-boom Cal (Test 3.5)**.

D. When **Test 3.5** is repeated, the step number is not 172 or 173.

This is normal operation. Every time this test is run the instrument uses a default value stored in the memory and allows the operator to calibrate the Z-boom to the correct position with the **0** and **“.”** keys. Once the STORE key is pressed, the calibrated Z-boom home step # is stored as **System 3.14** until the calibration procedure is performed again or **System 3.14** is edited.



## A

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# LOT NUMBER INTERPRETATION

For Use with Activation Codes and Other Lot Number Referrals

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In the Abbott Laboratories TDx<sup>®</sup>/TDxFLx<sup>®</sup> Lot Numbering System, the first two-digit numeric code indicates the month and the year of assignment. These codes are assigned sequentially beginning with 01 and proceeding through 96 before repeating 01. The second three-digit numeric code identifies each lot. For example, for month 50 the number is assigned starting with 50001X100 through 50999X100. Upon reaching 50999X100 in the same month, the sequence will revert to 50001X200 through 50999X200 and repeat the cycle with X300, X400, etc. Therefore, the number 50001X200 is greater than 50999X100.

**NOTE:** The suffix designation X = Q, M, or SV.

In some cases, it is possible for a single base lot of material to be processed in stages requiring the last two digits of the lot numbers to change from 00 to 01, 02, etc. For example, the lot number sequence may be 50001X100 followed by 50001X101 in which case the 50001X101 is the higher lot number.



## Assay Activation Record

[illegible]





## Introduction

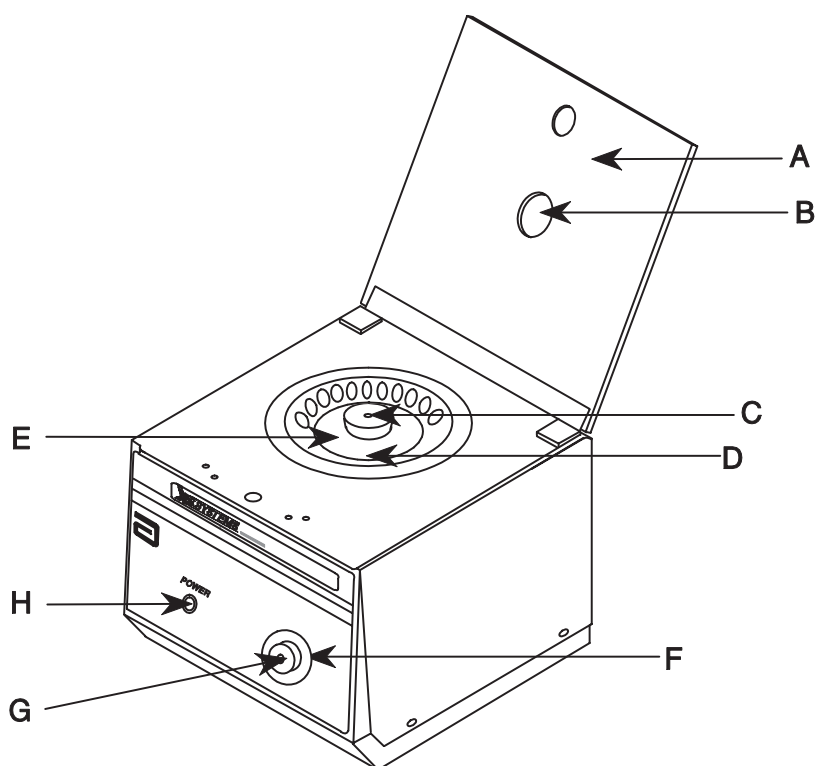
This section provides information on the following:

- **System Description**
- **Installation**
- **Operation**
- **Speed Check/Calibration**
- **Maintenance  
Cleaning and Decontamination**

For information concerning assays or assay requirements, please refer to the appropriate TDx<sup>®</sup>/TDxFLx<sup>®</sup> Systems Assays manual. For additional assistance, please call the **Customer Support Center**.

## Centrifuge Components

This section illustrates and defines the following components of the TDx<sup>®</sup> Centrifuge:



- A. Centrifuge Lid
- B. Cooling Port
- C. Thumbscrew
- D. Centrifuge Head
- E. Reflective Tape Area
- F. Time Control Dial

- G. Start Button
- H. Run Indicator Lamp
- I. Calibration Potentiometer (not shown)

TDx<sup>®</sup> Centrifuge Components

**Figure 1**

- A. **Centrifuge Lid:** has a safety lid interlock system. When the start button is pressed, the centrifuge lid locks. The lid remains locked for approximately 30 seconds after the centrifuge motor shuts off to ensure that the centrifuge lid can be safely opened.
- B. **Cooling Port:** is off center of the centrifuge lid to facilitate cooling of the centrifuge motor and to reduce noise. A light beam tachometer is used to check the centrifuge calibration through the centrifuge lid and is not affected by this offset.
- C. **Thumbscrew:** holds the centrifuge head to the drive shaft.

**Centrifuge Components**  
(continued)

- D. **Centrifuge Head:** holds a maximum of 20 centrifuge tubes and is held in place on the drive shaft with a thumbscrew. The 20 centrifuge tube positions are numbered clockwise (1–20).
- E. **Reflective Tape Area:** is determined by the user. The reflective tape is placed on the area of the centrifuge head where it is easily detected by the tachometer and an accurate indicator of the RPM.
- F. **Time Control Dial:** is continuously adjusted for setting run times from 0 to 5 minutes in increments of 15 seconds.
- G. **Start Button:** When the start button is pressed, the lid latch locks, the run indicator lamp illuminates, and the centrifuge starts spinning. When the set time expires, the centrifuge motor shuts off. The lid remains locked (approximately 30 seconds) until the centrifuge lid can be safely opened.
- H. **Run Indicator Lamp:** is an amber colored visual indicator that is illuminated while the lid interlock system is engaged. When the run indicator lamp goes off, the centrifuge lid can be opened.
- I. **Calibration Potentiometer:** is a screwdriver-adjustable, continuously variable potentiometer. The potentiometer is located either on the back or side panel of the centrifuge.

**Centrifuge Specifications****General Characteristics**

- Capacity of Centrifuge Head = 20 tubes (1.5 mL)
- Relative Centrifugal Force = 9,500 xg (minimum)
- Timer Control = 0–5 minutes
- Acceleration Time = 6 seconds (full load)
- BTU/Hr Output = less than or equal to 450

**Physical Characteristics**

- Centrifuge Depth = 11.5" (29.2 cm)
- Centrifuge Width = 9.25" (23.5 cm)
- Centrifuge Height (closed lid) = 7.8" (19.8 cm)
- Head Radius = 3.05" (7.75 cm)
- Maximum Weight = 13.51 lbs. (6.1 kg)

**Electrical Characteristics**

- Voltage = 100, 110, or 120 VAC (+10% to –15%)
- Frequency = 50 or 60 Hz
- Power Connection = 3-prong grounded outlet (U.S.A.)
- Leakage Current = less than 500 micro amps

**Environmental Requirements**

- Room Temperature = 15 to 30°C (59 to 86°F)
- Humidity = 15 to 85% humidity
- Location = Flat, level surface, no direct sunlight or drafts. Removed from sources of direct heat and moisture.

## Precautions and Limitations

1. The TDx<sup>®</sup> Centrifuge lid interlock system is intended to protect the user. Do not attempt to defeat the lid interlock system of the centrifuge or operate the centrifuge if the interlock system is not functioning.
2. When the centrifuge is not properly balanced, excessive noise and/or vibration can occur.
  - Stop the centrifuge run by rotating the time control dial to zero. When the indicator lamp goes off the lid latch releases, lift the lid and determine the source of the noise or vibration (e.g., uneven number of tubes, unequal volume of liquid).
  - If any component of the centrifuge appears to be damaged or if the centrifuge cannot be adjusted to perform properly, discontinue use and contact the **Customer Support Center**.
3. Abbott Laboratories recommends the X SYSTEMS<sup>®</sup> Centrifuge Tubes LN 9527-40 for use in the TDx<sup>®</sup> Centrifuge. Use of any other centrifuge tubes may result in damage to the tubes or to the centrifuge itself.
4. Do not cover or block the cooling port when the centrifuge is running.
5. The centrifuge and the centrifuge head should be cleaned as needed. Follow the established procedures in your laboratory for handling potential biological hazards spills.

**WARNING:**

- Consider all clinical specimens and reagent controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.
- Unplug the power cord before cleaning.

**CAUTION:**

- Decontaminate using a 1% sodium hypochlorite (20% household bleach) solution.
- Avoid using excessive amounts of water while cleaning. This may cause damage from water seepage around the motor shaft.
- Avoid the use of abrasive cleaners which could scratch the surfaces.

6. The TDx<sup>®</sup> Centrifuge must be decontaminated prior to return to Abbott Laboratories.

X SYSTEMS is a trademark of Abbott Laboratories.

## Unpacking

1. Carefully remove the TDx<sup>®</sup> Centrifuge (LN 9527-01) from the shipping carton.
2. Inspect the inside and outside of the centrifuge and the centrifuge head for damage. If damage is observed, keep the shipping carton and all packing material intact.
3. Contact the **Customer Support Center** to report damage or any missing centrifuge items.

## Installation Procedure

Install the TDx<sup>®</sup> Centrifuge using the following procedure:

1. Place the centrifuge on a flat surface near an appropriate AC outlet.
2. Make sure the thumbscrew is secure.
3. Set the time control dial to zero.
4. Check the data plate on the rear of the unit for correct operating voltage and line frequency.
5. Plug the power cord into the outlet.
6. After installing the centrifuge, verify that the centrifuge is operational and in calibration prior to being placed into general operation. Perform the Centrifuge Speed Check procedure located in the **Speed Check/Calibration** section in this manual to verify calibration.
7. Review the **Operation** section for appropriate loading and running of the centrifuge.

## Centrifuge Loading

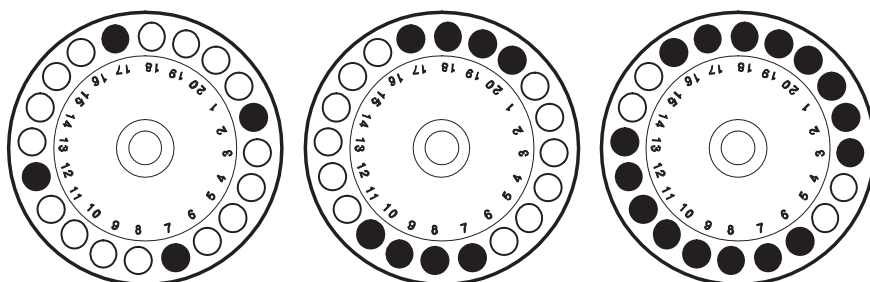
For the best results, load the centrifuge in the manner described below:

- NOTES:**
- Materials required for individual assays are described in the appropriate assay manual.
  - Use only Abbott X SYSTEMS<sup>®</sup> Centrifuge tubes.

1. Load the centrifuge head with an **even** number of the same capacity tubes containing samples of the same volume.

**NOTE:** If an uneven number of samples is being run, fill an empty tube with water to the same level as the sample and use as a balance tube.

2. If less than a full load is to be run, load identical samples 180° apart (Figure 2).
3. Make sure that the caps are securely snapped on the tubes.



Proper Centrifuge Loading  
**Figure 2**

---

**Initiating Run**

Once the centrifuge has been properly loaded, follow the procedure below to operate the centrifuge:

1. Close the lid.
2. Set the time control dial to the desired centrifugation interval.
3. Press the start button.

**NOTE:** The lid latch locks, the run indicator lamp illuminates, and the centrifuge starts spinning.

4. The centrifuge runs until the set time expires or the run is interrupted.
5. The centrifuge motor shuts off.

**NOTE:** The lid remains locked and the run indicator lamp remains on for approximately 30 seconds to ensure that the centrifuge is safe to open.

6. When the run indicator lamp goes off, open the lid and remove the sample tubes.



---

**Run Interruption**

1. Turn the time control dial to zero.

**CAUTION:** When the centrifuge is not properly balanced or the centrifuge head is not properly seated on the drive shaft, excessive noise and/or vibration may occur. Stop the centrifuge run.

2. The centrifuge motor shuts off.

**NOTE:** The lid remains locked and the run indicator lamp remains on for approximately 30 seconds to ensure that the centrifuge is safe to open.

3. When the run indicator lamp goes off, open the lid and determine the source of the noise or vibration.

**CAUTION:** If any component of the centrifuge appears to be damaged or if the centrifuge cannot be adjusted to perform properly, discontinue use and contact the **Customer Support Center**.

4. Inspect the head for tube balance and adjust if necessary.
5. Verify that the head is correctly mounted on the drive shaft. See the **Maintenance** section for instructions on installing the centrifuge head.
6. The run may continue once the problem is corrected and the necessary adjustments are made.

**Centrifuge Speed Check**

Check the speed of the TDx<sup>®</sup> Centrifuge quarterly using the Centrifuge Speed Check procedure.

**Equipment Needed**

1. Calibrated photoelectric centrifuge tachometer
  - Abbott recommends the Shimpo DT-205 tachometer marketed by Shimpo America Corp., 3500 Devon Ave., Lincolnwood, IL 60659.
  - Although the Shimpo tachometer is recommended, any optical unit which provides consistent readings may be used. The instructions provided with the tachometer should be followed in taking measurements.
  - Do not use a tachometer which requires physically touching the rotating centrifuge head.
2. 20 centrifuge tubes

Use only X SYSTEMS<sup>®</sup> Centrifuge Tubes LN 9527-40.
3. Reflective tape

Reflective tape is supplied with tachometer or purchased from the tachometer distributor.

**Procedure**

1. Fill 20 centrifuge tubes with 1.5 mL water.
2. Snap the caps on securely and load the 20 centrifuge tubes into the centrifuge head.
3. Place the reflective tape on an area of the centrifuge head where it is easily detected by the tachometer and an accurate indicator of the RPM. See **Figure 1** for general area of placement.
4. Close the lid.
5. Turn the time control dial to the 5 minute position and press the start button.

**NOTE:** The lid latch locks, the run indicator lamp illuminates and the centrifuge starts spinning.

6. Let the centrifuge run for 30 seconds before checking the speed with the tachometer.

**Centrifuge Speed Check**  
(continued)

7. Aim the light beam of the tachometer directly through the smoky plastic lid to take readings. Follow the instructions supplied with the tachometer.

8. Read the centrifuge operating speed in RPM.

**Check Passes:** RPM between 10,600 and 14,000

**Check Fails:** RPM outside of above range

9. If the centrifuge fails the Centrifuge Speed Check, the centrifuge must be calibrated using the **Centrifuge Speed Calibration procedure** in this section of the manual.

**NOTE:** Adjustments to the centrifuge speed may be required to compensate for motor brush wear, motor aging, or line-voltage fluctuation between locations or the installation of new operating components.

10. Turn the time control dial to zero.

## Centrifuge Speed Calibration

### Centrifuge Speed Adjustment

If it is necessary to adjust the centrifuge speed, locate the potentiometer on either the back or side panel of the centrifuge.

### Equipment Needed

1. Calibrated photoelectric centrifuge tachometer

Refer to the **Centrifuge Speed Check procedure** for the tachometer recommended by Abbott Laboratories.

2. 20 centrifuge tubes

Use only X SYSTEMS<sup>®</sup> Centrifuge Tubes LN 9527-40.

3. Thin-blade screwdriver or potentiometer trimming tool

4. Reflective tape

Reflective tape is supplied with the tachometer or purchased from the tachometer distributor.

### Procedure

1. Fill 20 centrifuge tubes with 1.5 mL water.
2. Snap the caps on securely and load the 20 centrifuge tubes into the centrifuge head.
3. Place the reflective tape on an area of the centrifuge head where it is easily detected by the tachometer and an accurate indicator of the RPM. See **Figure 1** for general area of placement.
4. Close the lid.
5. Turn the time control dial to the 5 minute position and press the start button.  
**NOTE:** The lid latch locks, the run indicator lamp illuminates and the centrifuge starts spinning.
6. Let the centrifuge run for 30 seconds before checking the speed with the tachometer.
7. Aim the light beam of the tachometer directly through the smoky plastic lid to take readings. Follow the instructions supplied with the tachometer.
8. Read the centrifuge operating speed in RPM.
9. Insert a small screwdriver into the potentiometer.

## Centrifuge Speed Calibration

(continued)

### Back Panel Potentiometer

Those units with speed adjustments on the back panel. There are two nuts on the shaft of the potentiometer. The inner nut mounts the potentiometer to the panel and **SHOULD NEVER BE LOOSENED**. The outer nut serves as a locknut for the shaft.

1. To adjust the potentiometer, loosen the outer nut and turn the shaft with a small screwdriver. Clockwise adjustment increases the speed. Counterclockwise adjustment decreases the speed.
2. Using the tachometer, continue to measure the RPMs and make adjustments with the potentiometer until the speed reads between 10,600 and 14,000 RPM.
3. Tighten the outer nut, and turn the time control dial to zero.

### Side Panel Potentiometer

Side access potentiometer adjustments.

1. Using a small screwdriver or flat edged tool, remove the black button plug on the lower left side panel of the centrifuge and set aside.
2. Insert a thin screwdriver and turn. Clockwise adjustment decreases the speed, and counterclockwise adjustment increases the speed.
3. Using the tachometer, continue to measure the RPMs and make adjustments with the potentiometer until the speed reads between 10,600 and 14,000 RPM.
4. Turn the time control dial to zero and replace the access plug.

## Cleaning and Decontamination

To properly maintain the centrifuge, use the following procedures and clean on an as needed basis:

The cleaning procedure requires removal of the centrifuge head.

### Removing the centrifuge head from the centrifuge

1. **Unplug** the centrifuge from the AC outlet.
2. Loosen the thumbscrew that holds the head in place by turning it counterclockwise for several rotations.
3. Grip the center portion of the head and gently pull upward.

**NOTE:** This may take several attempts before the head is released.

4. After the head is released from the drive shaft, perform the cleaning procedure.

**NOTE:** If the head does not lift up, follow the procedure below for removing the centrifuge cover to provide additional leverage in removing the centrifuge head.

### Removing the centrifuge cover

1. Remove the eight screws that hold the top cover on the unit. There are four screws on the top and two screws on each side.
2. Save the four washers that go on the sides of the cover.
3. Lift the cover straight up, and set aside.
4. Use both hands to reach under the rim of the head. Press down on the thumbscrew while pulling up on the rim. This procedure should provide enough leverage to remove the head.
5. After the head is released from the drive shaft, perform the cleaning procedure.

**NOTE:** If the centrifuge head cannot be removed, contact the [Customer Support Center](#).

**Cleaning and  
Decontamination**  
(continued)

Cleaning the centrifuge and the centrifuge head

**WARNING:** • **Consider all clinical specimens and reagent controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule or other equivalent biosafety procedures.**

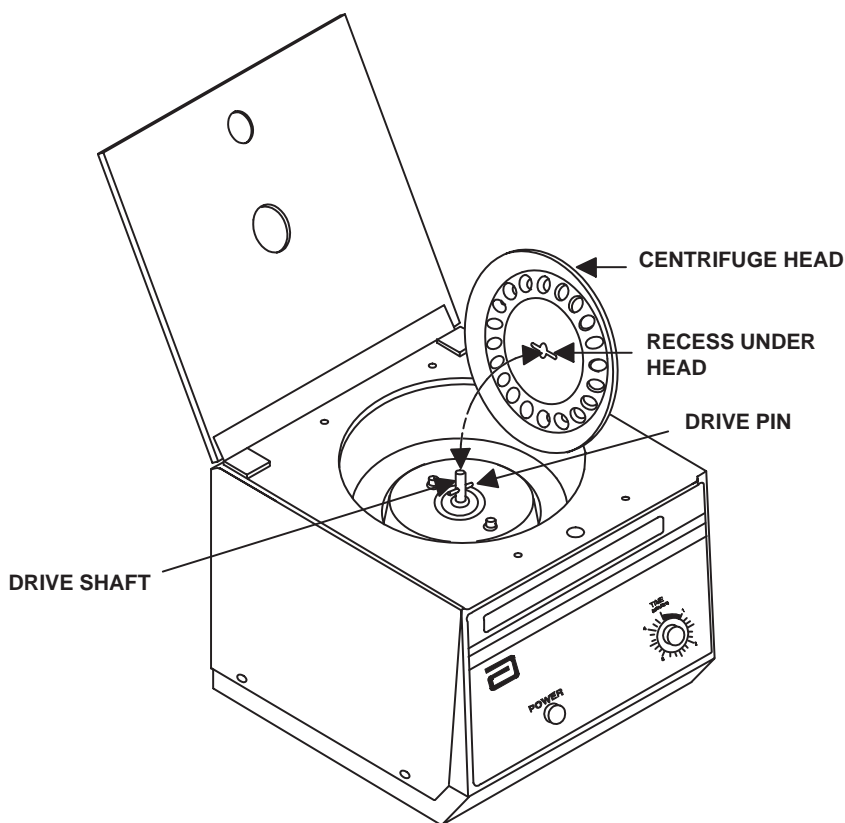
**CAUTION:** • **Avoid using excessive amounts of water while cleaning. This may cause damage from water seepage around the motor shaft.**

- **Avoid the use of abrasive cleaners which could scratch the surfaces.**

1. Clean using a damp cloth for the centrifuge and a damp swab for the centrifuge head.
2. Use a dry cloth for the centrifuge and a dry swab for the centrifuge head to remove all moisture.
3. Decontaminate using a 1% sodium hypochlorite (20% household bleach) solution.

**Cleaning and  
Decontamination**  
(continued)

Reinstalling the centrifuge head



Centrifuge Head and Drive Shaft Alignment

**Figure 3**

1. Locate the drive pin on the drive shaft and the recess under the centrifuge head.
2. Line up the pin and the recess so that they are perpendicular to each other.
3. Place the head on the shaft, and gently spin the head. The head should drop into correct alignment with the drive pin.

**CAUTION:** Improper mounting of the head may cause damage to both the head and the centrifuge. Be sure the above steps are followed correctly.



---

**Cleaning and  
Decontamination**  
(continued)

4. Fasten the thumbscrew finger-tight and spin the head again.

**NOTES:**

- Do not use a wrench or any other tool to tighten this screw.
- The head is installed correctly if it does not wobble.

5. Reinstall the top cover, screws, and washers if previously removed.

**CAUTION: Do not run the centrifuge until the top cover is secured and closed.**

6. Plug in the centrifuge.

