TDxFLx® System

Operator's Quick Reference Guide

CD-TOC EXIT

Click on Chapter title below to select.

- General Information
- Features
- Operation
- Special Procedures
- Maintenance

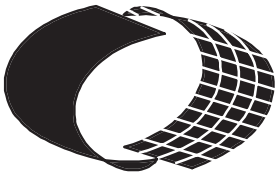
ABBOTT LABORATORIES
ABBOTT PARK, IL 60064

PN 45414-102

X SYSTEMS®

CUSTOMER SUPPORT CENTER
1-800-527-1869 (U.S. Customers Only)
(7 Days, 24 hours)

Abbott Customer Commitment Network



BEFORE YOU CALL US

Have the following information ready for your Customer Support Center Specialist:

- Serial Number
- Complete Error Codes
- Control Values
- Result Tapes
- Reagent Lot Number
- Maintenance Log

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INTRODUCTION

The TDxFLx® System Operator's Quick Reference Guide is provided as part of our customer commitment to provide quick and easy access of information to experienced TDxFLx® System operators. Refer to the TDxFLx® System Operations Manual and TDx®/TDxFLx® Systems Assays Manual for detailed instructions. If inconsistencies exist between this guide and other TDxFLx® documentation, the TDxFLx® System Operations Manual and TDx®/TDxFLx® Systems Assays Manual will have precedence.

Revision Number	**Pages Revised and Added**
Originally Issued (Rev. 2.0 software) 12/93	Not applicable
R-102 12/94	All pages

GENERAL INFORMATION

- ROAD MAP
- ASSAY PARAMETERS & KEY FUNCTIONS
- PROCEDURE SUMMARY

ROAD MAP

SYSTEM MONITOR

1. SYSTEM STATUS
   - 1.1 DATE
   - 1.2 TIME
   - 1.3 LIQ C
   - 1.4 PHO C
   - 1.5 AIR C
   - 1.6 REV
2. SYSTEM CONTROL
   - 2.1 BEEP
   - 2.2 LOCK
   - 2.3 RST SPL
   - 2.4 BAUD
   - 2.5 P BIAS
   - 2.6 THM OFF
   - 2.7 AIRSET
   - 2.8 PAPER
   - 2.9 STORAGE
   - 2.10 CMP MDE
   - 2.11 CUP SIZ
3. SYSTEM PARAMS
   - 3.1 CAR HM
   - 3.2 RBM HM
   - 3.3 SERM PT
   - 3.4 PREDIL
   - 3.5 CUVETTE
   - 3.6 POP PT
   - 3.7 TRA PT
   - 3.8 ANTI PT
   - 3.9 WASTE
   - 3.10 DAC
   - 3.11 RDAC
   - 3.12 CAR RBR
   - 3.13 CAR CBR
   - 3.14 ZBM HM

DIAGNOSTIC TEST

1. MAINTENANCE
   - 1.1 EXERCISOR
   - 1.2 LIFETEST
2. SPEC CHECKS
   - 2.1 TEMP CHECK
   - 2.2 PHOTO CHECK
     - 2.2.1 GAIN
   - 2.3 PIPE CHECK
3. CALIBRATION
   - 3.1 TEMP CAL
   - 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
   - 3.3 CRSL CAL
   - 3.4 PHOTO CAL
     - 3.4.1 GAIN
     - 3.4.2 INTENS
     - 3.4.3 HV COEF
     - 3.4.4 POL
   - 3.5 ZBOOM CAL
   - 3.6 U.D. BOOM CAL
   - 3.7 4 POT-BOOM CAL
   - 3.8 TURBO CRSL CALIB
   - 3.9
   - 3.10 AUTO BOOM CAL
   - 3.11 TEST NOT DEFINED
   - 3.12 RESET POINTERS
   - 3.13 RGT CRSL CAL
   - 3.14 BUFER RUN
   - 3.15 BATCH BUFFER RUN

ASSAY PROTOCOLS

1. GENTAMICIN
2. TOBRAMYCIN
3. AMIKACIN
4. PHENYTOIN
5. PHENOBARBITAL
6. PRIMIDONE
7. NETILMICIN
8. VALPROIC ACID
9. CARBAMAZEPINE
10. DIGOXIN
11. QUINIDINE
12. PROCAINAMIDE
13. NAPA
14. LIDOCAINE
15. THEOPHYLLINE
16. VANCOMYCIN
17. FREE VALPROATE
18. CY A/METAB (WB)
19. DIBEKACIN
20. STREPTOMYCIN
21. KANAMYCIN
22. METHOTREXATE
23. CY A/METAB (P/S)
24. ETHOSUXIMIDE
25. DISOPYRAMIDE
26. FREE PHENYTOIN
27. DIGITOXIN
28. FLUOXETINE
29. T-UPTAKE
30. ACETAMINOPHEN
31. SALICYLATE
32. FREE CARB
33. TOTAL T3
34. GLUCOSE
35. BUN

ROAD MAP

SYSTEM MONITOR (continued)

- 3.15 4POP PT
- 3.16 4TRA PT
- 3.17 4ANT PT
- 3.18 4WSH PT

4. RECALL DATA
   - 4.1 REPRINT DATA
   - 4.2 DISPLAY DATA
   - 4.3 RECALL CAL DATES
   - 4.4 REAGENT TABULATN

5. ACTIVATE ASSAY
   - 5.1 ASSAY NUMBER
   - 5.2 U.D. QC PARAMS

6. IDENTIFICATION
   - 6.1 SERIAL #
   - 6.2 ASSAY CATEGORIES
   - 6.3 OP ID#
   - 6.4 PBR #
   - 6.5 RGT LOT
   - 6.6 PAT ID
   - 6.7 T PRINT
   - 6.8 TOT T3
   - 6.9 EXP DATE
   - 6.10 COLLATE
   - 6.11 DTE FMT
   - 6.12 TST CNT
   - 6.13 LOADLST
   - 6.14 SPL LST

7. THYROID FEATURES
   - 7.1 LO NORM
   - 7.2 HI NORM
   - 7.3 CALC %
   - 7.4 F.T.I.
   - 7.5 FT4C

DIAGNOSTIC TEST (continued)

4. HAND CONTROLS
   - 4.1 REVOLVER
   - 4.2 PHOTOMETER
   - 4.3 PUMPER
   - 4.4 BOOMER
   - 4.5 TEMP HNDLR
   - 4.6 BARCODE CHK
   - 4.7 REAGENT CAR

5. BOARD TESTS
   - 5.1 REPEAT RUN
     - 5.1.1 SINGLE RUN
   - 5.2 COMPUTER BOARD
     - 5.2.1 PROM TEST
     - 5.2.2 RAM TEST
   - 5.3 MEMORY BOARD 1
     - 5.3.1 PROM TEST 1
     - 5.3.2 NOVRAM TEST 1
   - 5.4 PRINTER & DRIVER
     - 5.4.1 LONG PRINT TEST
     - 5.4.2 SHORT PRINT TEST
   - 5.5 I/O BOARD
     - 5.5.1 UART TEST
     - 5.5.2 CTC TEST
     - 5.5.3 WASTE CUP TEST
   - 5.6 FRONT PANEL
     - 5.6.1 KEYBOARD TEST
     - 5.6.2 DISPLAY TEST
   - 5.7 MTR BOARD

ASSAY PROTOCOLS (continued)

36. CHOLESTEROL
37. URIC ACID
38. AMYLASE
39. CREATININE
40. ETHANOL
41. IRON/TIBC
42. HDL CHOLESTEROL
43. LACTIC ACID
44. TOTAL ESTRIOL
45. AMPHET-CLASS U
46. CORTISOL
47. LDH
48. METHADONE U
49. COTININE
50. CYA (WB)
51. FLECAINIDE
52. NORCLOMIPRAMINE
53. CRP
54. 5-HIAA (URINE)
55. CLOMIPRAMINE
56. TRICYCLICS S
57. AMPHET/METH U
58. BARBITURATES U
59. COCAINE METAB U
60. CANNABINOIDS U
61. PCP U
62. OPIATES U
63. BENZODIAZEPINE U
64. BARBITURATES S
65. BENZODIAZEPINE S
66. FREE ESTRIOL
67. DIGOXIN NXT
68. HALOPERIDOL
69. THC S
70. IGA

ROAD MAP

SYSTEM MONITOR (continued)

8. UNIT DOSE PARAMS
   - 8.1 UD RBM
   - 8.2 UD CAR
   - 8.3 UD POP
   - 8.4 UD TRA
   - 8.5 UD ANTI
   - 8.6 UD SH A
   - 8.7 UD SH P
   - 8.8 UD PUNC
   - 8.9 UD WAIT
   - 8.10 UD R B

9. SHARED PACK OPTS
   - 9.1 ESTRL
   - 9.2 PHEN
   - 9.3 CARB
   - 9.4 VALPR
   - 9.5 CHOLES

10. TDxFLx PARAMS
    - 10.1 RCRSL HM
    - 10.2 WPOP RBM
    - 10.3 WTRA RBM
    - 10.4 WANT RBM
    - 10.5 WDG BRCD
    - 10.6 WSTE ZBM
    - 10.7 RGNT ZBM

11. PANELS
    - 11.1 PANEL 1
      - 11.1.1. P1.1
      - 11.1.2. P1.2
      - 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

Repeats thru 11.9 Panel 9

DIAGNOSTIC TEST (continued)

6. SPECIAL TESTS
   - 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

ASSAY PROTOCOLS (continued)

71. IGG
72. IGM
73. TRANSFERRIN
74. TOTAL DOXEPINS
75. ISEPAMICIN
76. APRINIDINE
77. MAO ACTIVITY
78. MEGX
79. T4
80. NORFLUOXETINE
81. PROPOXYPHENE U
82. AMITRIPTYLINE
83. NORTRIPTYLINE
84. DESIPRAMINE
85. IMIPRAMINE
86. CY A (P/S)
87. ARBEKACIN
88. FLM
89. ASSAY 89 ____
90. ASSAY 90 ____
91. ASSAY 91 ____
92. ASSAY 92 ____
93. ASSAY 93 ____
94. ASSAY 94 ____
95. ASSAY 95 ____
96. ASSAY 96 ____
97. ASSAY 97 ____
98. ASSAY 98 ____

ASSAY PARAMETERS & KEY FUNCTIONS

Assay Parameters

XX.1. SPL VOL
XX.2. SPL REP
XX.3. LOLIM
XX.4. HILIM
XX.5. CAL VOL
XX.6. CAL REP
XX.7. CONC A
XX.8. CONC B
XX.9. CONC C
XX.10. CONC D
XX.11. CONC E
XX.12. CONC F
XX.13. UNITS
XX.14. CRV FIT
XX.15. MX DEV
XX.16. MN POLA
XX.17. MN SPAN
XX.18. MODE
XX.19. GAIN
XX.20. MX BKG
XX.21. MN TR
XX.22. BA DTE
XX.23. BA TME
XX.24. RA DTE
XX.25. RA TME
XX.26. UD DTE
XX.27. UD TME

For some assays,
XX.3 is BKG FAC
XX.4 is THRSHLD

The system status keys are used to change the status for the analyzer. The three keys are:

- **RUN** – Starts assay or calibration runs, diagnostic tests and system calibration procedures.
- **PRIME** – Cycles buffer through the dispense system.
- **STOP** – Cancels the current operation.

KEY	FUNCTION
PRINT	Generates hardcopy and advances paper.
EDIT	Allows changes in parameters.
STORE	Stores new values in memory.
ASSAY	Access to the Assay menu.
TEST	Access to the Diagnostic Test menu.
SYSTEM	Access to the System Monitor menu.
CLEAR	Removes a value from display if an error is made during entry (before pressing **STORE**).
DISPLAY	Displays information in the software.
NEXT	Goes to the next parameter.

The numeric keys are used to enter data on the display panel when the software displays a prompt.

- Turn features on and off
  1 = ON
  0 = OFF

PROCEDURE SUMMARY

Print Assay Parameters

Press **ASSAY XX** (select assay)
PRINT

Reagent Loadlist

Press **SYSTEM 6.13 EDIT**

To print, press **1 STORE STOP**
To not print, press **0 STORE STOP**

Sample Loadlist

Press **SYSTEM 6.14 EDIT**

To print, press **1 STORE STOP**
To not print, press **0 STORE STOP**

Activate Assay

Press **SYSTEM 5.1 RUN**

- Enter assay number XX and press **STORE**
- Enter activation code on activation letter and press **STORE**
- Display shows Assay Activated READY
- Print Assay Parameters and compare to activation letter.
- Calibrate assay.

Recall Calibration Dates

Press **SYSTEM 4.3 RUN**

For Batch, press **0 STORE**

For Unit Dose, press **1 STORE**

For Random Access, press **2 STORE**

From ASSAY **XX STORE**

To ASSAY **XX STORE**

Edit Assay Parameter

Press **ASSAY XX.XX** (select parameter)
EDIT
(enter value)
STORE
STOP

Buffer Run

Edit Door Lock:
Press **SYSTEM 2.2 EDIT 0 STORE STOP**

Random Access

TEST 3.14 RUN
Enter Assay #s for all wedges

Press **RUN**

Batch

TEST 3.15 RUN
Enter Assay # and press **STORE**

Printout Options

Press **SYSTEM 6.10 EDIT**
To collate by location, press **0**
To collate by patient ID, press **1**
To collate by assay, press **2**

Press **STORE STOP**

Reprint Results

Press **SYSTEM 4.1 RUN**

Tests Used/Tests Left

Press **SYSTEM 6.12 DISPLAY**

- To display # of tests used per reagent pack, press **EDIT 0 STORE STOP**
- To display # of tests left per reagent pack, press **EDIT 1 STORE STOP**

Clean/Soak/ Decontaminate the Probe

Load a sample carousel with cuvettes in locations 1 & 2. Pipette 3 mL of 1% bleach in cuvette #1 and 3 mL of DI water in cuvette #2.

Press **TEST 6.8 RUN**

FEATURES

- FEATURES & BENEFITS
- PANELING

TDxFLx REV 2.0/2.1 FEATURES & BENEFITS

Features	Benefits	For Additional Information:
• Multiple tests from one sample aliquot	– True random access processing – Saves keystrokes and eliminates manual pipetting, thereby saving time and labor costs – More cost-effective operation	TDxFLx® System Operations Manual Section 3.0 *Operation*
• TDx® System like "Batch" mode operation for one wedge-pack	– Time and labor savings – Eliminates test request for each sample – Reduces keystrokes during load-up – 3 step operation – just like TDx® System	TDxFLx® System Operations Manual Section 3.0 *Operation*
• Enhanced barcode scanner capabilities: Code 3 of 9, Interleaved 2 of 5, Code 128 barcode symbologies, as well as Codabar	– Scanning in patient IDs (PAT ID) saves much time and labor – Reduces manual data input errors – Cost effective operation	TDxFLx® System Operations Manual Section 1.0 *System Description*
• Display "Tests Used" or "Tests Left"	– Eliminates confusion surrounding tests used or remaining in a reagent pack – Provides better reagent inventory information – Ensures more efficient use of reagent packs in subsequent runs – More user friendly	TDxFLx® System Operations Manual Section 3.0 *Operation*

TDxFLx REV 2.0/2.1 FEATURES & BENEFITS

Features	Benefits	For Additional Information:
• Random Access Panel Programming	– Ideal for CAP or proficiency panels – Ability to pre-program up to 9 customized panels – Reduces operator keystrokes for random access runs	TDxFLx® System Operations Manual Section 3.0 *Operation*
• Identify controls via scanner	– Assists in better quality control tracking and regulatory requirements – Reduces errors by identifying control name, location, and result on printout	TDxFLx® System Operations Manual Section 3.0 *Operation*
• Automated boom calibration and probe positioning	– Similarity/continuity of procedures between TDxFLx® and IMx® Systems – Reduces operator steps in boom calibration – User-friendly operation	TDxFLx® System Operations Manual Section 4.0 *Diagnostic Checks*
• Option to print/not print reagent loadlist	– Initiates sample processing sooner – Reduces number of operator prompts – More user friendly	TDxFLx® System Operations Manual Section 3.0 *Operation*
• Option to print patient I.D. (PAT ID) on sample loadlist	– Allows the operator to better track specimens on the sample carousel – Reduces risk of load-up errors	TDxFLx® System Operations Manual Section 3.0 *Operation*

TDxFLx REV 2.0/2.1 FEATURES & BENEFITS

Features	Benefits	For Additional Information:
• Dilution protocol for wedge assays	– Eliminates manual dilution and mathematical errors	TDxFLx® System Operations Manual Section 3.0 *Operation*
• Option to print sample loadlist, at the beginning of a random access run	– Reduces the number of prompts to the operator – Saves keystrokes (no need to reply yes/no) – Initiates sample processing sooner – Customizes TDxFLx® set-up configuration	TDxFLx® System Operations Manual Section 3.0 *Operation*
• Auto-probe decontamination procedure	– Saves time and labor – Reduces “hands-on“ maintenance time – Reduces exposure to biohazardous materials	TDxFLx® System Operations Manual Section 5.0 *Maintenance*
• Multiple printout capability: results are configured by sample, test or carousel location	– Customized to individual lab preferences – More user friendly	TDxFLx® System Operations Manual Section 3.0 *Operation*
• Recall calibration dates for random access assays	– Allows for easier quality control tracking – Documents last calibration dates for CLIA and other regulatory requirements	TDxFLx® System Operations Manual Section 3.0 *Operation*

REV 2.0/2.1 PANELING

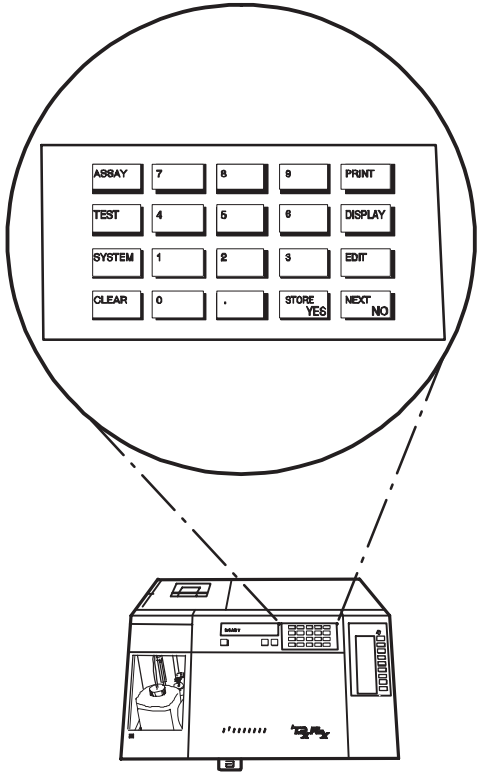
Panel Programming

Panel Programming is used to define a panel and is performed in System 11.

Press 1) **SYSTEM 11.X**
(X corresponds to the panel number, selecting from 1–9)
2) **EDIT**
3) **NEXT**
4) **ASSAY #** (2-digit number. Example: 04 for Phenytoin to add an assay to the panel)

or **CLEAR** (to delete assay)
5) **STORE**
6) Repeat steps 3 through 5 until all assays needed have been entered (maximum of 8 assays).
7) **STOP**

DO NOT SKIP ANY ASSAY LOCATIONS WITHIN A PANEL



Panel Printing

Press **TEST 6.9 RUN**

The system prints a listing of panel locations, assay names, and assay numbers for all panels. The following displays at the completion of the routine:

DONE

Press **STOP** to return to the following display:

READY

Verify printout is correct.

REV 2.0/2.1 PANELING

Initiating Panel Testing

- Pipette sample into only the first position of a panel. Place empty sample cartridges and cuvettes behind the first sample cartridge for each additional test ordered.
- Pipette enough sample to accommodate all tests defined in the panel. Use the following table to determine the minimum sample volume.
- Do not exceed sample volume of 500 µL.

Sample Volumes for Panel Testing

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

*Maximum Sample Volume is 500 µL

Testing Procedure

Place the loaded reagent and sample carousels into the instrument.

Press **RUN**

After the System has identified the reagents, the following displays:

```
LOC X ASSAY # __ __
```

Press * (PANEL) **KEY**

The following displays:

```
LOC X PANEL # __ __
```

Select the desired panel. 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**

The following displays:

```
LOC X ASSAY # __ __
```

Repeat procedure until all samples on the carousel are entered. When complete:

Press **Run**

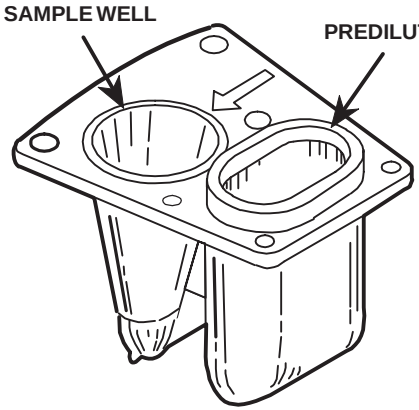
OPERATION

- RANDOM ACCESS
- BATCH

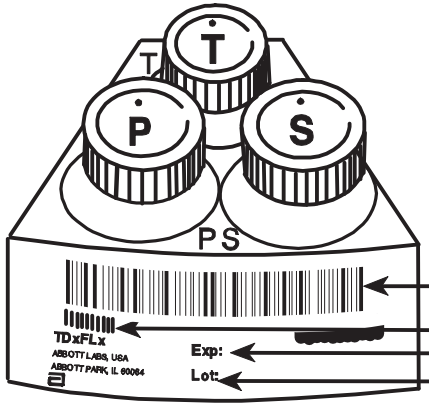
RANDOM ACCESS

- RANDOM ACCESS CAROUSEL & CONSUMABLES
- RANDOM ACCESS RUN CAROUSEL SETUP
- RANDOM ACCESS REAGENT HANDLING
- RANDOM ACCESS PROCESSING

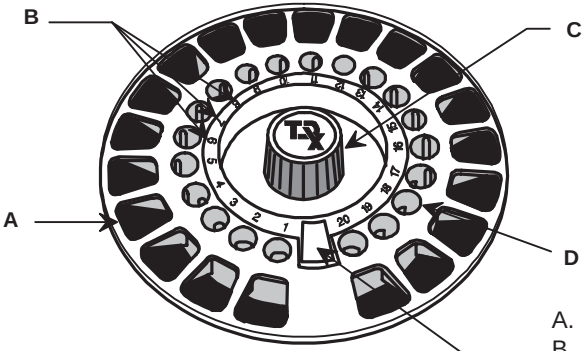
RANDOM ACCESS CAROUSEL & CONSUMABLES



SAMPLE CARTRIDGE

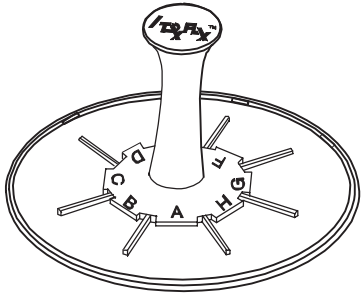


RANDOM ACCESS REAGENT PACK

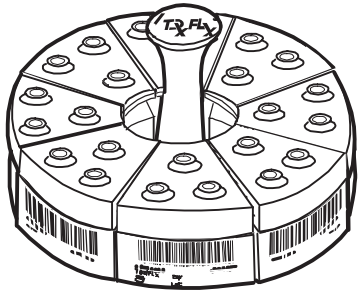


SAMPLE CAROUSEL

A. Sample Cartridge Positions
B. Carousel Position Numbers
C. Carousel Lock Mechanism
D. Cuvette Positions
E. Carousel ID Position



UNLOADED REAGENT CAROUSEL

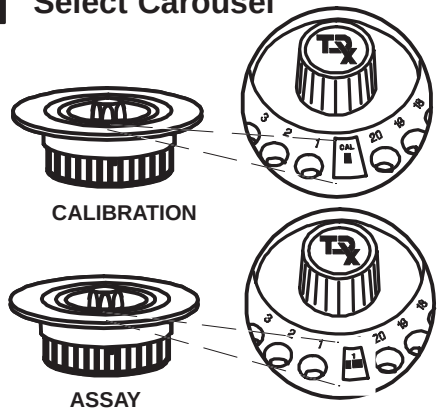


LOADED

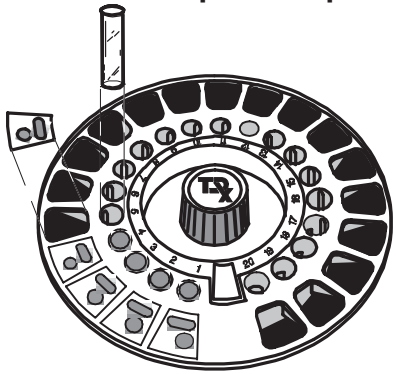
RANDOM ACCESS RUN CAROUSEL SETUP

1 Prepare Sample Loadlist

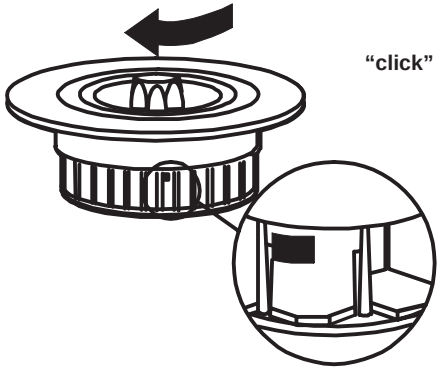
2 Select Carousel



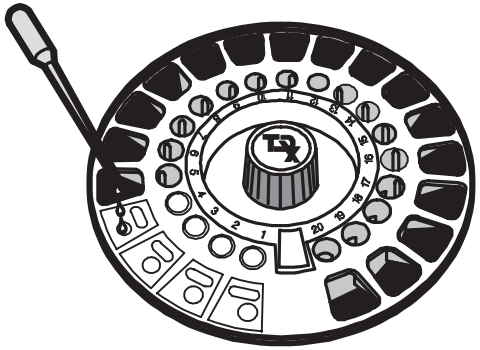
3 1 Sample Cartridge and Cuvette per Sample



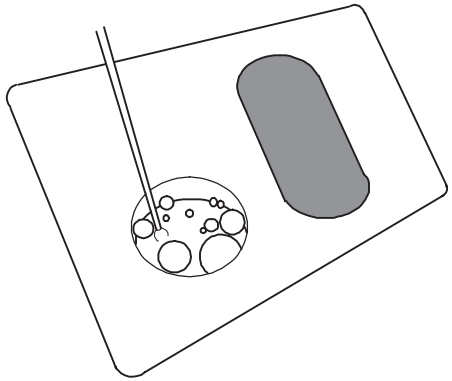
4 Lock Carousel



5 Pipette Sample

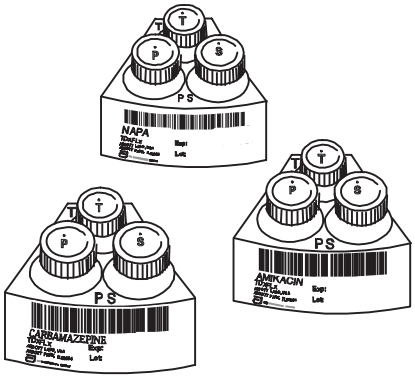


6 Remove Bubbles

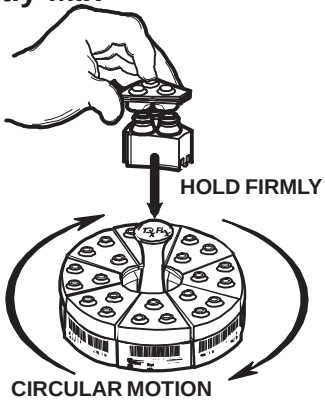


RANDOM ACCESS REAGENT HANDLING

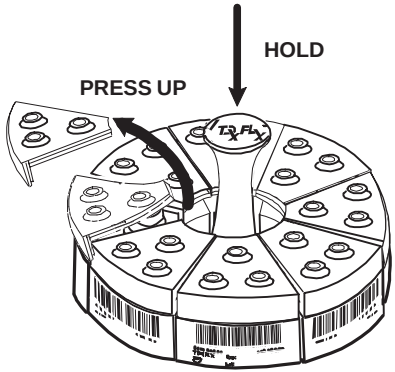
7 Select Wedges



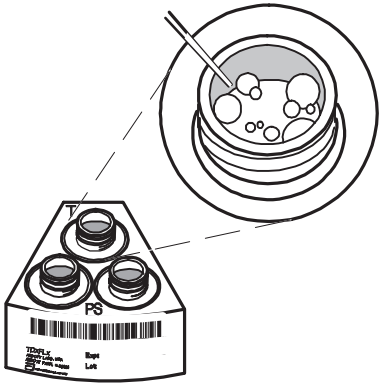
8 Gently Mix



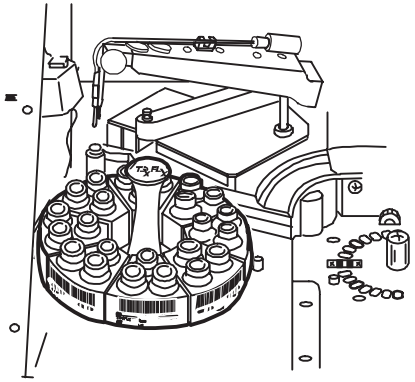
9 Remove Snap Cups



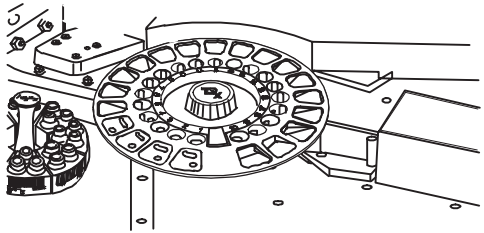
10 Remove Bubbles



11 Place Reagent Carousel into TDxFLx® Analyzer

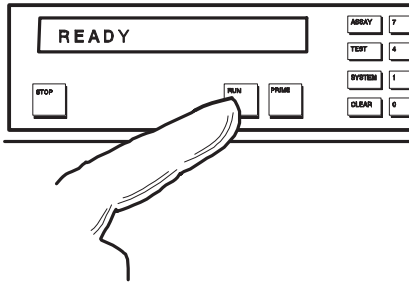


12 Place Sample Carousel into TDxFLx® Analyzer



RANDOM ACCESS PROCESSING

13 Press RUN



14 *Enter IDs

OP ID? 111

Press **STORE**

RGT #? 1 9 1 8 3 2 9 8

Enter RGT lot number (if required)
(Reagent pack located at the barcode fail reagent position.)

Press **STORE**

(Verify reagent loadlist, if applicable)

* Optional – defined by SYSTEM 6.6 PAT ID

15

LOC 1 ASSAY #

Press the desired key on the reagent display keypad

ID 1?

Enter Patient ID # manually or with barcode scanner

Press **STORE**

Are all samples entered? — **NO**

YES

Press **RUN**

16 *Verify Sample Loadlist, if applicable

ASSAY LIST OK?

YES: Press **STORE**

NO: Press **NEXT** (To incorrect location.) → Change assay and PAT ID.

```
TDXFLX RUN

DATE: 09/19/96
TIME: 15:51:50
SERIAL #: 60022
LOCK= 1
OP ID:
CAROUSEL: 1
      SAMPLE LOADLIST

LOC  1 VALPROIC ACID
LOC  2 PHENOBARBITAL
LOC  3 TOBRAMYCIN
LOC  4 PHENOBARBITAL
LOC  5 PHENOBARBITAL
LOC  6 TOBRAMYCIN
LOC  7 VALPROIC ACID
```

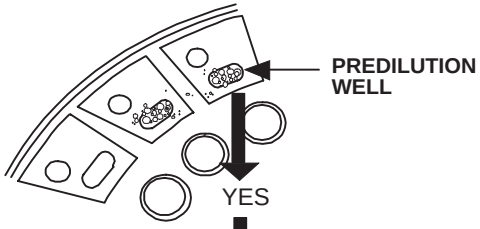
* Optional – defined by SYSTEM 6.14 SPL LST

RANDOM ACCESS PROCESSING

17 Complete the Run

18 Check Carousel

Splashing and Foaming?



Refer to the TDxFLx® System Operations Manual

19 Review Results

Error Codes? — YES → Refer to the TDxFLx® System Operations Manual

NO

Splashing or Foaming? — YES → Refer to the TDxFLx® System Operations Manual

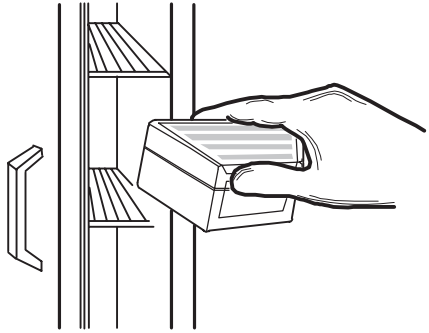
NO

Controls OK? — NO → Refer to the TDxFLx® System Operations Manual

YES

Report Results.

20 Store Reagents



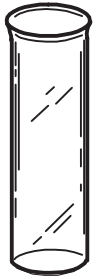
Discard sample cartridges/cuvettes.

BATCH

- BATCH CAROUSEL AND CONSUMABLES
- BATCH RUN CAROUSEL SETUP
- BATCH REAGENT HANDLING
- BATCH PROCESSING
- “BATCH” OPERATION USING SINGLE WEDGE
- CALIBRATION
- DIGOXIN II PRETREATMENT PROCEDURE

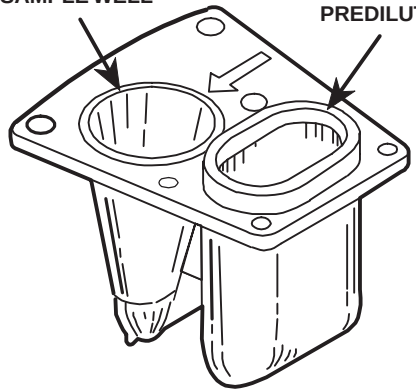
BATCH CAROUSEL AND CONSUMABLES

CUVETTE

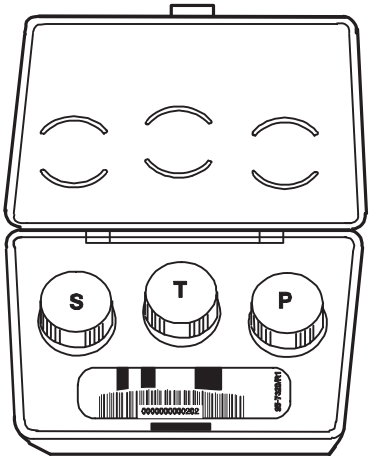


SAMPLE WELL

PREDILUTION WELL

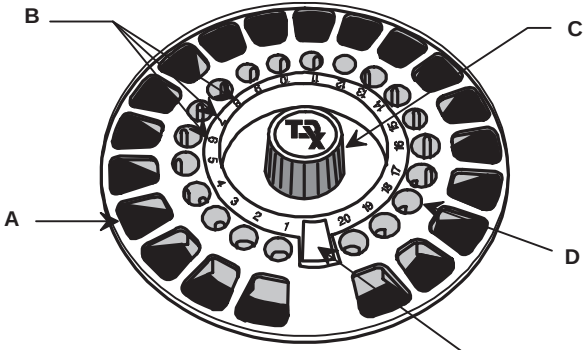


SAMPLE CARTRIDGE

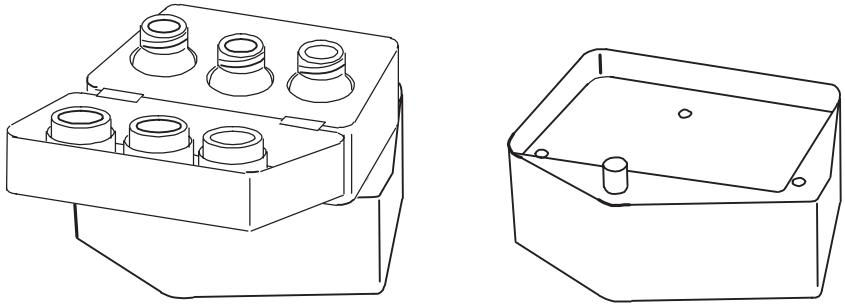


BATCH REAGENT PACK

A. Sample Cartridge Positions
B. Carousel Position Numbers
C. Carousel Lock Mechanism
D. Cuvette Positions
E. Carousel ID Position



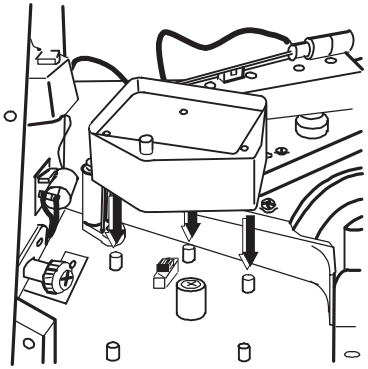
SAMPLE CAROUSEL



BATCH PACK ADAPTER

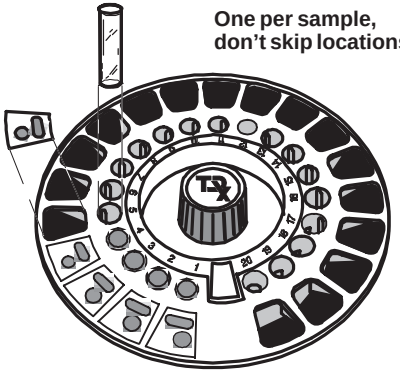
BATCH RUN CAROUSEL SETUP

1 Install Batch Pack Adapter

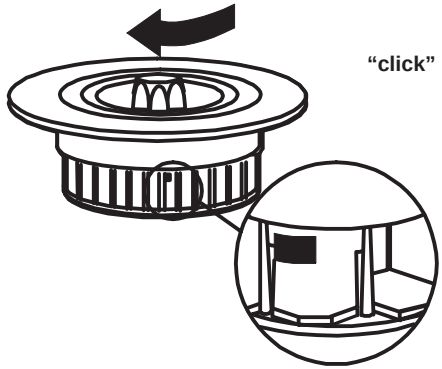


2 Load Sample Cartridges and Cuvettes

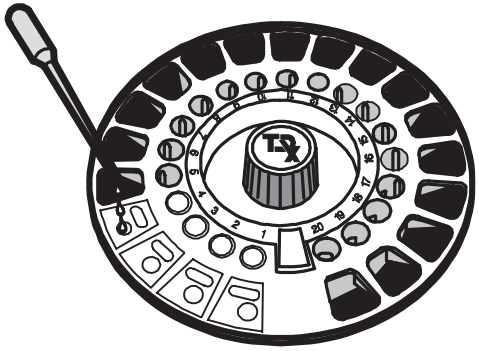
One per sample, don't skip locations



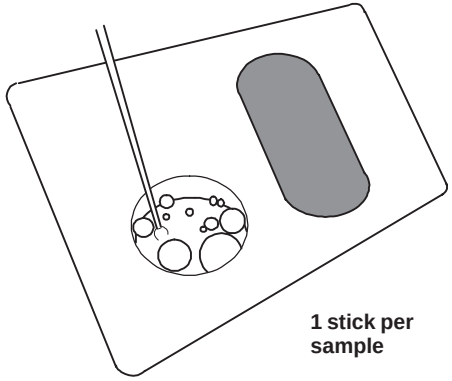
3 Lock Carousel



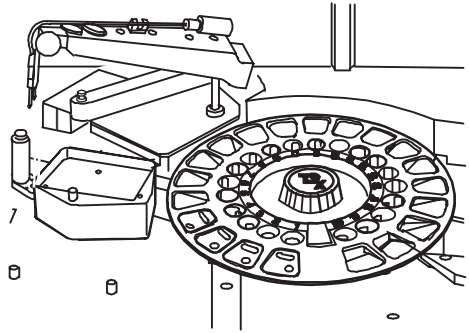
4 Pipette Sample



5 Remove Bubbles



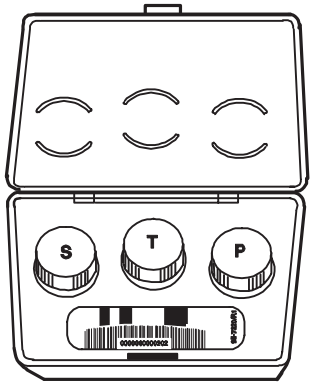
6 Place Carousel into TDxFLx® Analyzer



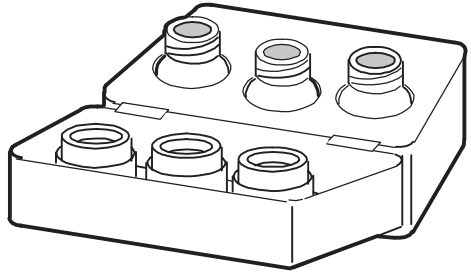
BATCH REAGENT HANDLING

7 Mix Gently 3 Times

8 Check Vials (S, T, P)

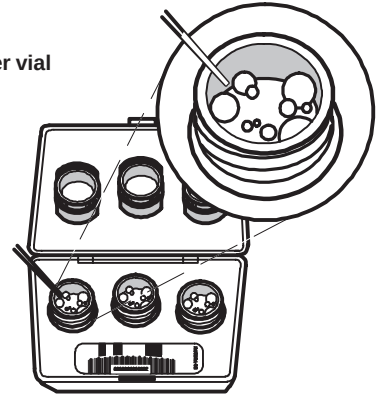


9 Remove Caps

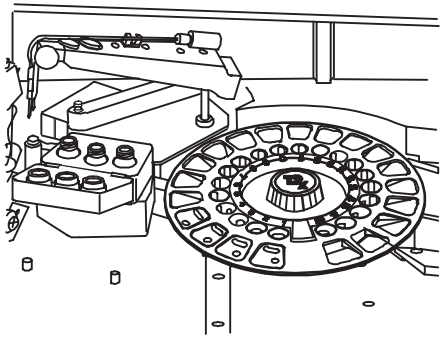


10 Remove Bubbles

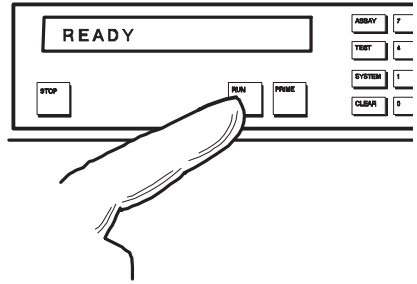
1 stick per vial



11 Position Reagents



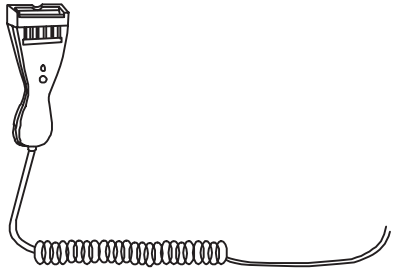
12 Press RUN



BATCH PROCESSING

13 Enter IDs (if desired)

Use the barcode scanner to identify control locations.

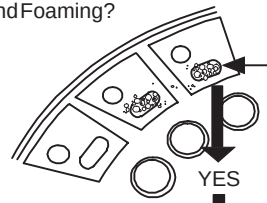


14 Complete Run

DONE – REMOVE RPAK

15 Check Carousel

Splashing and Foaming?



YES

Refer to the TDxFLx® System Operations Manual.

16 Review Results

Error Codes?

YES → Refer to the TDxFLx® System Operations Manual.

NO

Refer to the Assay Manual Insert.

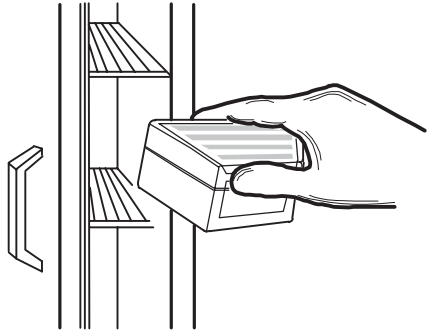
Controls OK?

NO → Refer to the TDxFLx® System Operations Manual.

YES

Report Results.

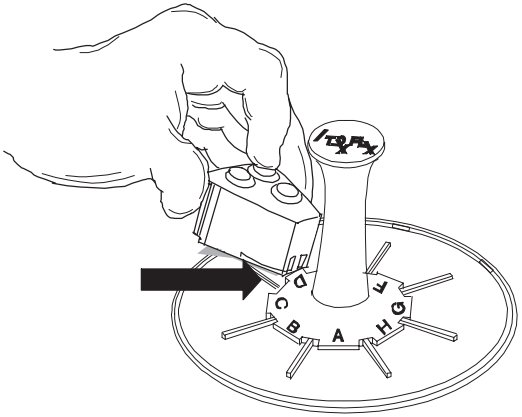
17 Store Reagents



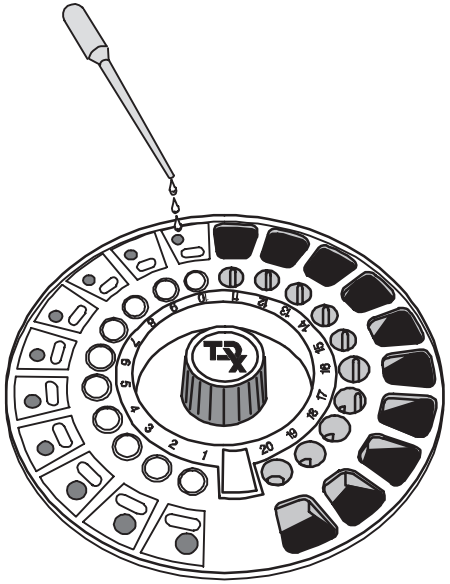
Discard sample cartridges/cuvettes.

"BATCH" OPERATION USING SINGLE WEDGE WITH REV 2.0/2.1

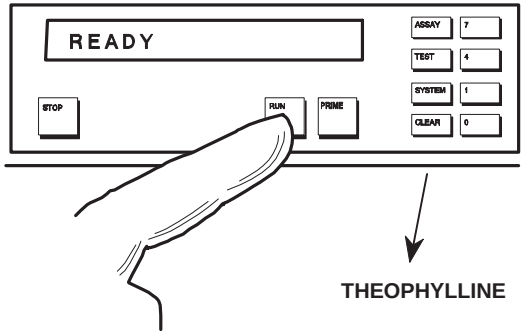
1 Place Reagent Wedge Pack on Carousel



2 Load 20-Position Sample Carousel



3 Press RUN



- All samples processed for the same assay
- One keystroke only

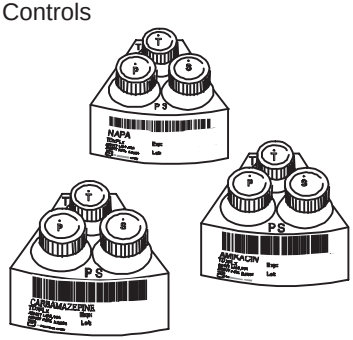
CALIBRATION

Recommendations

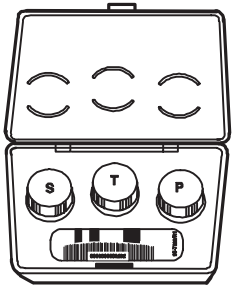
1. Calibrate one assay at a time
2. Calibrators in duplicate
3. Single replicates of controls

Materials Needed

- Reagent Carousel or Batch Pack Adapter
- Reagent Pack (Random Access or Batch)
- Calibration Sample Carousel
- Sample Cartridges
- Cuvettes
- Calibrators
- Controls



RANDOM ACCESS



BATCH

Procedure (Refer to Basic Run)

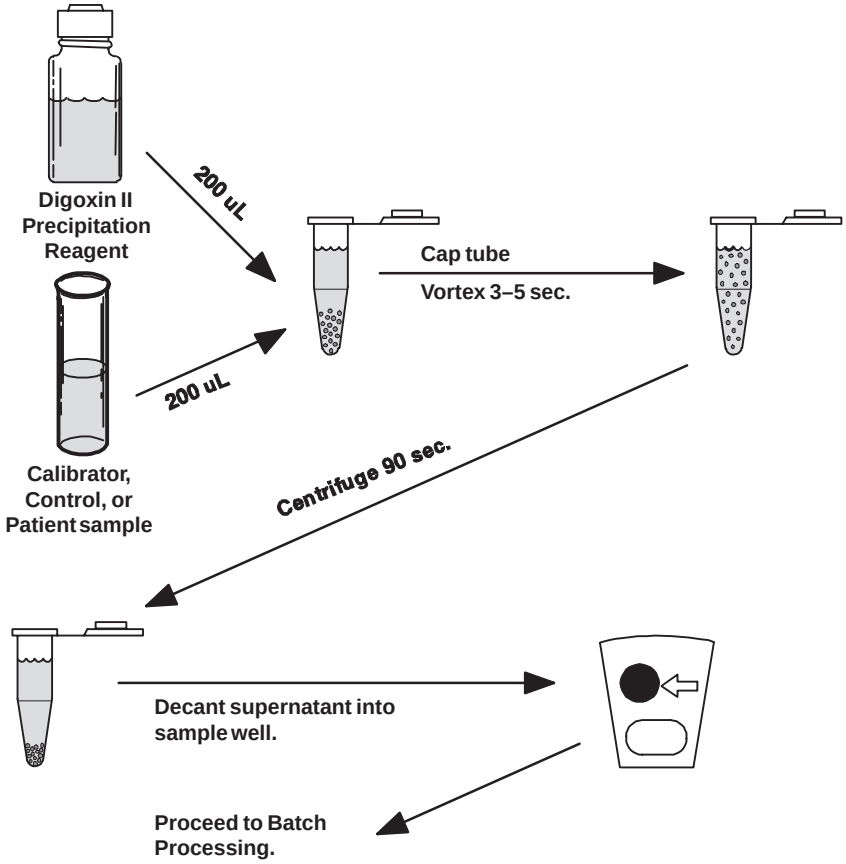
1. Mix reagent and place into instrument.
   (Refer to Random Access or Batch Reagent Handling.)
2. Set up sample carousel and place on centerpost.
3. Press **RUN**
4. Enter IDs (if desired).
   VERIFY LOADLISTS IF APPLICABLE.
5. When the run is complete, check the carousel for splashing and foaming.
6. Review results:
   - Control values
   - RMSE
   - PERRs

   (Refer to the Assay Manual Insert for expected ranges.)
7. Dispose of the consumables.
8. Return the reagents to the recommended storage conditions.

DIGOXIN II PRETREATMENT PROCEDURE

Materials Needed

- Centrifuge Tubes
- Pipette 0-200 µL
- Sample Cartridges
- X SYSTEMS® Cuvettes
- Digoxin II Reagent Pack
- Precipitation Reagent
- Batch Pack Adapter



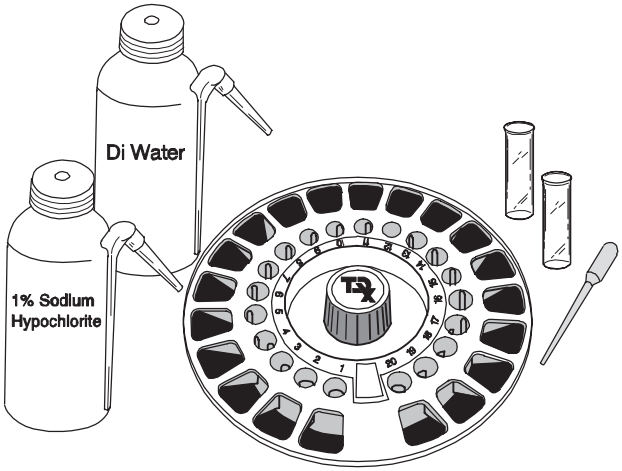
SPECIAL PROCEDURES

- AUTOMATED PROBE DECONTAMINATION
- AUTOMATED PROBE POSITIONING & BOOM CALIBRATION
- REAGENT CAROUSEL CALIBRATION
- DILUTION PROTOCOL
- BARCODE OVERRIDE

AUTOMATED PROBE DECONTAMINATION

Materials Needed

- Sample Carousel
- 2 Cuvettes
- 1% Sodium Hypochlorite
- Deionized Water
- Pipet



Procedure

- Insert cuvettes into positions 1 and 2 on the sample carousel. Lock the carousel.
- Pipet 3 mL of 1% sodium hypochlorite into position 1.
- Pipet 3 mL of deionized water into position 2.
- Put the sample carousel into the instrument.

Press **TEST 6.8 RUN**

The following will display:

PROBE DECONTAM
TIME LEFT: XX:XX
15 minute countdown
PROBE DECONTAM
Prime
DONE

Press **STOP**

Remove the carousel and discard the cuvettes. The following will display:

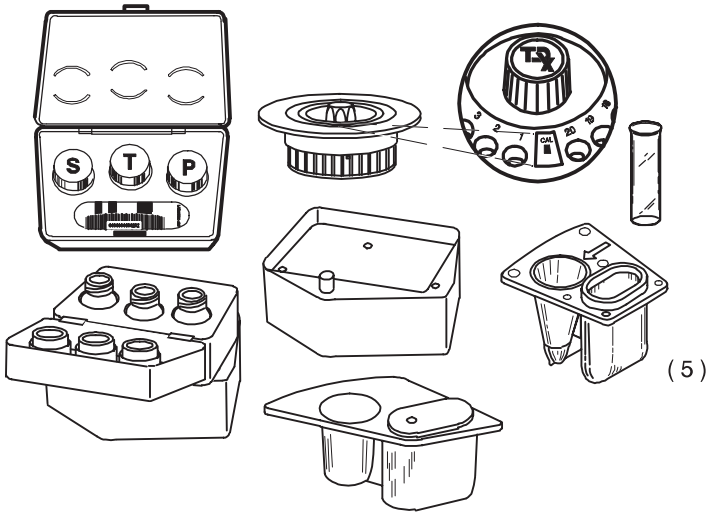
READY

NOTE: If the STOP key is pressed anytime during the decontamination process the system will rinse with DI water, prime with buffer and return to the [READY] state.

AUTOMATED PROBE POSITIONING & BOOM CALIBRATION

Materials Needed

- Batch-pack Adapter
- Calibration Carousel
- Probe-positioning Cartridge
- 3-pot Reagent Pack
- 5 Sample Cartridges
- 1 Cuvette



(5)

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.

AUTOMATED PROBE POSITIONING & BOOM CALIBRATION

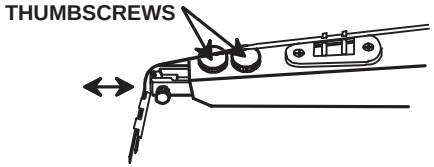
STEP	OPERATOR ACTION	SYSTEM RESPONSE
A	Press **TEST 3.10 RUN**	**AUTO BOOM CAL** • Boom seeks home. • Carousel rotates. • Barcode reader finds the edge of the carousel label holder. • Carousel rotates. • Barcode reader locates carousel barcode. • Carousel rotates. • Boom moves home. Probe stops over “P” vial. **ADJUST POSITION**
B	• Adjust the left-to-right positions of the boom arm for all locations. Press **“.”** (right) **0** (left) When the correct position is obtained: Press **STORE** • Repeat left-to-right adjustment for: “T” vial “S” vial Waste/Wash Station Sample Well Verify that position is correct. Press **STORE**	The boom moves left or right, records the position, and moves the boom to the next position. Moves to: “T” vial “S” vial Waste/Wash Station Sample Well Probe drops down to the bottom of the sample well. Carousel moves to position 2 probe-positioning cartridge. Probe moves to predilution well position.

AUTOMATED PROBE POSITIONING & BOOM CALIBRATION

STEP	OPERATOR ACTION	SYSTEM RESPONSE
C	Press **6** (down) repeatedly. DO NOT force the probe into the cartridge opening.	The probe moves down in step increments.
	• IF POSITION CORRECT: Press **STORE** Proceed to step D.	The program records the Dilution Well System 3.4 parameter. The probe moves to the cuvette position.
	• IF POSITION INCORRECT LEFT-TO-RIGHT: Press **"."** (right) **0** (left) Return to the beginning of Step C.	The probe moves up to the right or left.
	• IF POSITION INCORRECT FRONT-TO-BACK: Refer to the following procedure.	

Front-to-Back Probe Positioning

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.
2. Move the probe holder in or out of the boom arm as needed to position the probe in the probe-positioning cartridge opening.
3. Supporting the underside of the boom arm, hold the probe and tighten the two knurled thumbscrews to secure the probe.
4. Press **STOP** and repeat the positioning procedure beginning with Step A.



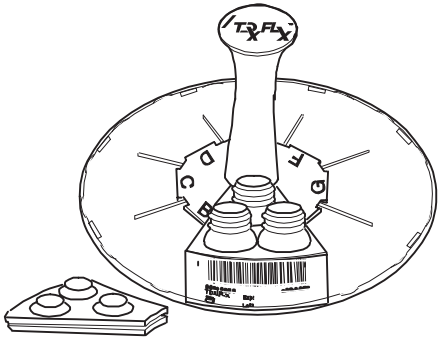
AUTOMATED PROBE POSITIONING & BOOM CALIBRATION

STEP	OPERATOR ACTION	SYSTEM RESPONSE
D	• Adjust probe position. Press **"."** (right) **0** (left) **STORE**	The carousel records Cuvette Position (Sys 3.5) **DISPENSING** 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.
E	• IF BOOM CAL PASSES: Remove the carousel and discard the waste. • IF BOOM CAL FAILS: Refer to the TDxFLx® System Operations Manual, Section 6.0 Printed Error Codes for corrective action.	**Z-BOOM LEVEL = XXX** Probe dips into each of the 5 sample wells verifying that each LLS 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. **BOOM CAL PASSED** Report is printed. Stores all previously recorded values. **READY** OR **BOOM OUT OF SPEC** Report is printed.

REAGENT CAROUSEL CALIBRATION

Materials Needed

- Reagent Carousel
- Wedge Reagent Pack



Procedure

The Reagent Carousel Calibration procedure stores the correct positions for the movement of the probe and the reagent carousel. The positions are determined for the S vial (SYSTEM 10.4) and the reagent barcode reader (SYSTEM 10.5). Other positions are calibrated from these two.

Press **SYSTEM**
10
PRINT

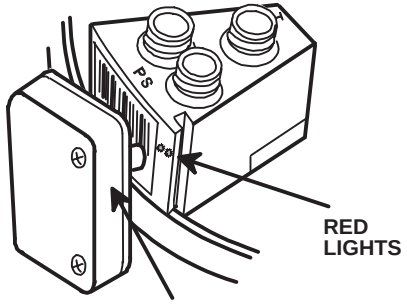
1. Select a reagent carousel.
2. Remove the lids or snap cap from a reagent wedge and place it into position A on the reagent carousel.
3. Place the reagent carousel into the instrument and leave the access door open.

NOTE: The Boom Calibration procedure must be performed before Reagent Carousel Calibration.

REAGENT CAROUSEL CALIBRATION

TASK	OPERATOR ACTION	SYSTEM RESPONSE
4. Begin the carousel calibration.	Press **TEST** **3.13** **RUN**	**SYS 3 PARAMS OK?**
CAROUSEL 5. Verify that boom calibration has been performed.	Press **STORE** **NOTE: If Boom Calibration has not been performed, press STOP.**	**RGT CRSL CAL** The reagent carousel rotates. The probe is positioned over the S vial.
6. Center the probe over the S vial.	• Move the probe: Press **0** (left) or "**.**" (right) • Move the carousel: Press **1** (clockwise) or **2** (counterclockwise) When centered: Press **STORE**	**ADJUST POSITION** Continues with the barcode adjustment. The reagent carousel rotates. The reagent wedge is positioned in front of the reagent barcode reader.

REAGENT CAROUSEL CALIBRATION

TASK	OPERATOR ACTION	SYSTEM RESPONSE
BARCODE 7. Position the reagent barcode with the reagent barcode reader.	Press "." (counterclockwise) Repeat until the red light appears on the edge of the wedge. • Adjust the carousel: Press **0** (clockwise) or "." (counterclockwise) When the red light is reflecting on the edge of the wedge NOT on the barcode label: Press **STORE**	**ADJUST POSITION** The carousel moves in steps in front of the barcode reader. 
8. Print the SYSTEM 10 parameters and keep for reference.	Press **SYSTEM** **10** **PRINT**	

NOTE: The boom and reagent carousel positions cannot be verified by running another boom calibration. Doing so would recalibrate rather than verify. To check these positions, perform a random access buffer run, TEST 3.14.

DILUTION PROTOCOL

Dilution protocol is only available for some assays. Refer to the specific assay manual insert for dilution instructions.

TASK	OPERATOR ACTION	SYSTEM RESPONSE
1. Print assay parameters.	Press **ASSAY** **XX** **PRINT**	A list of the assay parameters prints.
2. Edit the sample volume to the desired sample volume.	Press **ASSAY** **XX.1** **EDIT** **#.#** (new sample volume) **STORE** **STOP**	**SPL VOL #**
3. Perform assay.	• Setup carousel for the assay run. • Press **RUN**.	Assay name displays.
4. Return sample volume to the original value.	Press **ASSAY** **XX.1** **DISPLAY** • IF CORRECT: Press **STORE** • IF INCORRECT: Press **EDIT** **#.#** (original sample volume) **STORE** **STOP**	**SPL VOL #** **READY**

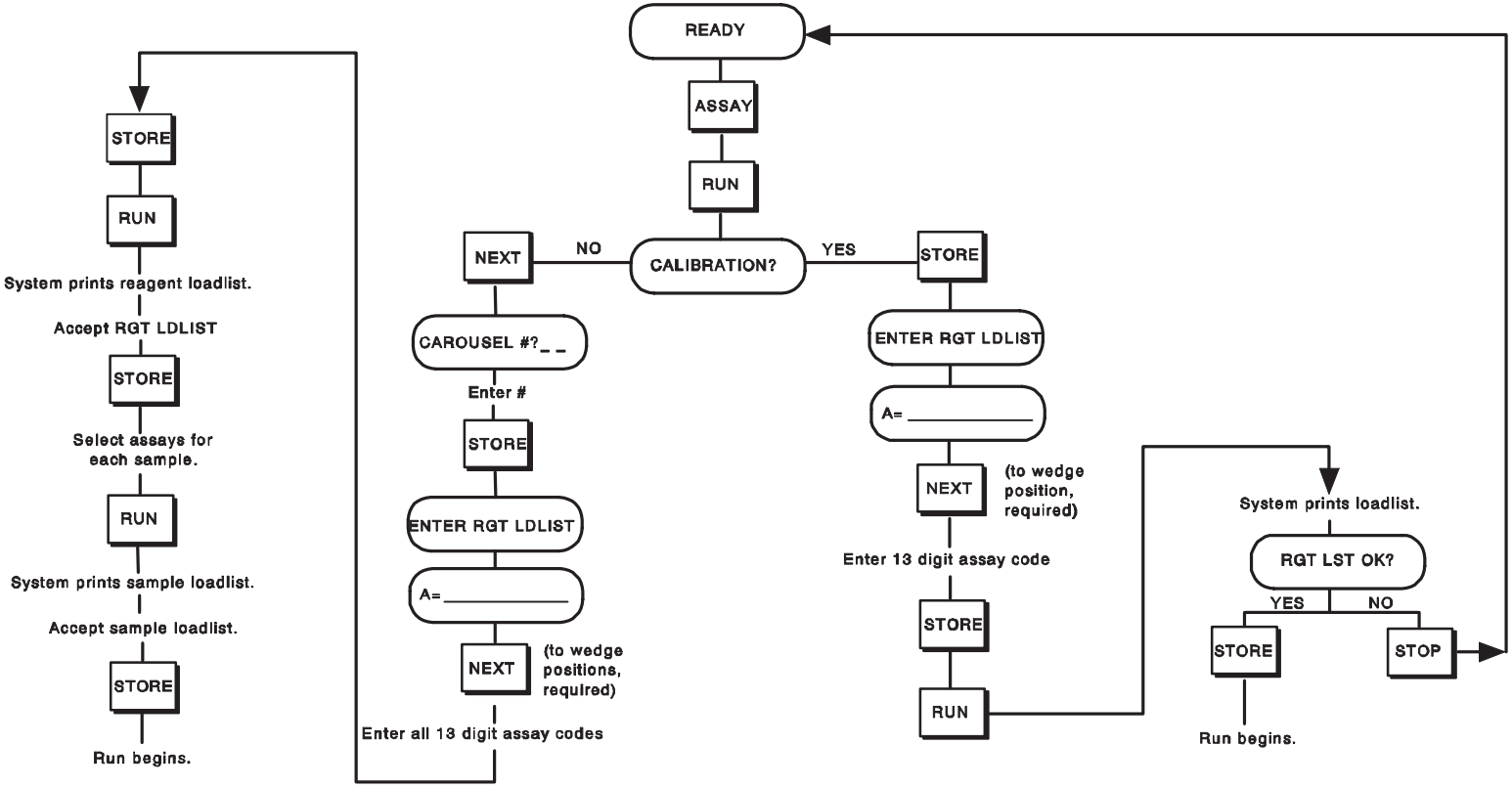
DILUTION PROTOCOL

Dilution Notes

1. When the run is completed, the polarization and concentration values are multiplied by the dilution ratio and printed.
2. If RST SPL (SYSTEM 2.3) has been set to 1, the sample volume will automatically return to the original value at the completion of the Dilution Protocol. (This feature is not available with HDL Cholesterol or CRP.)
3. Dilution Protocol cannot be used with the following assays:
   - Amphetamine/Methamphetamine II
   - Cannabinoids
   - Cortisol
   - Cyclosporine and Metabolites Serum
   - Cyclosporine and Metabolites Whole Blood
   - Cyclosporine Monoclonal Whole Blood
   - Digitoxin
   - Digoxin II
   - MEGX (Research Use Only)
   - Methotrexate
   - Methotrexate II
   - Quinidine
   - T-Uptake
   - T-4
   - Total and Free Estriol
   - Tricyclic Antidepressants
   - Unit Dose assays

BARCODE OVERRIDE

Random Access Procedure



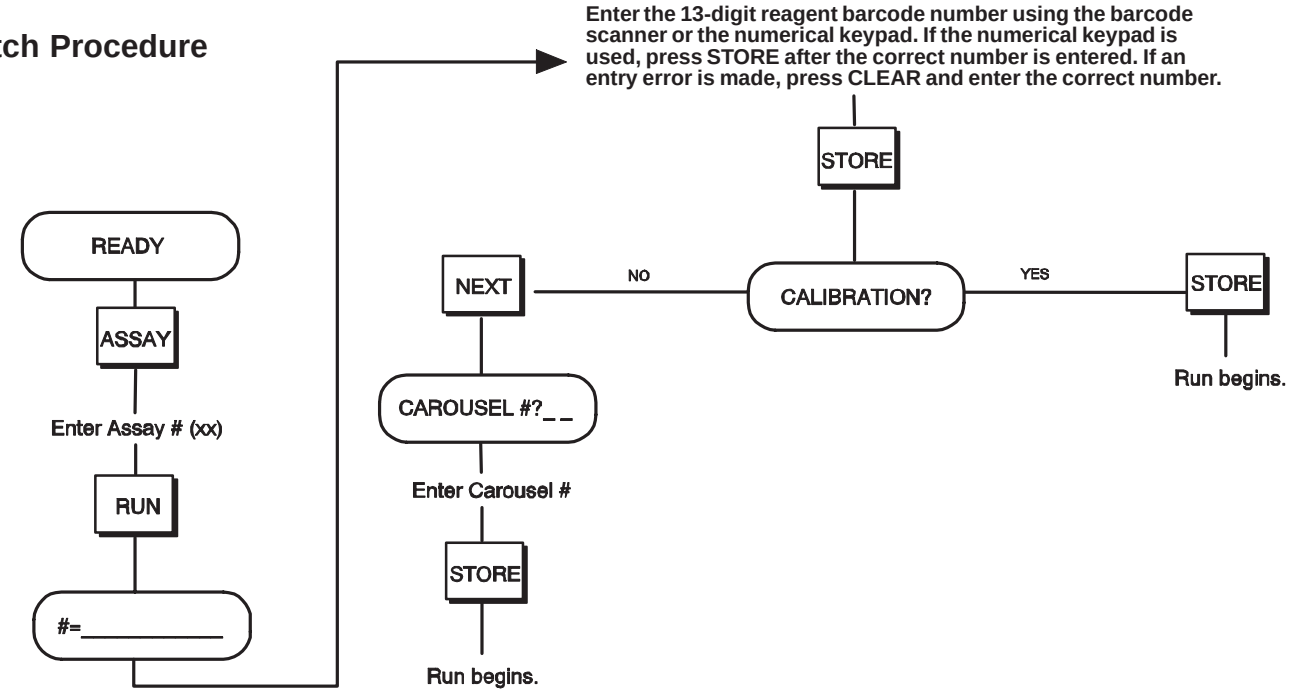
BARCODE OVERRIDE

Barcode Override is used when the barcode reader fails to read the barcode. There are two reasons that the system may be unable to read either a carousel or reagent pack barcode label:

- The barcode label is dirty or damaged.
- The barcode reader is dirty or damaged.

Until the proper troubleshooting procedures can be performed, the Barcode Override Procedure can be used to continue processing the run.

Batch Procedure



MAINTENANCE

DAILY

- Inspect and Wash Probe
- Inspect Valve Block/Syringes
- Clean Waste/Wash Station
- Empty Waste Container

WEEKLY

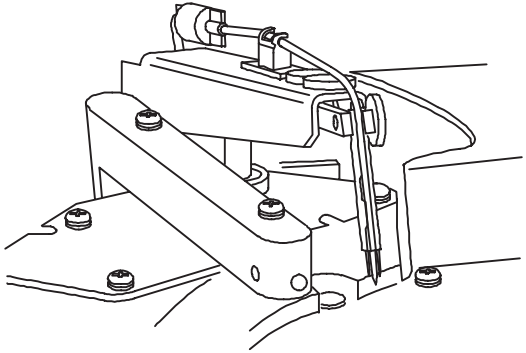
- Photo Check
- Dispense Water Wash
- Air-Fan Filter Cleaning
- Clean Waste Container and Carousels

MONTHLY

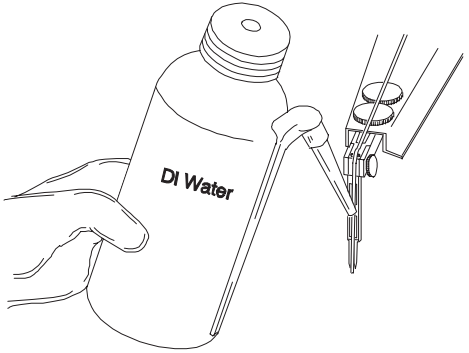
- Pipet Check
- Temperature Check
- Diluent Syringe Wash
- Precision Dispenser Calibration

DAILY

1 Inspect Probe/Electrode Assembly

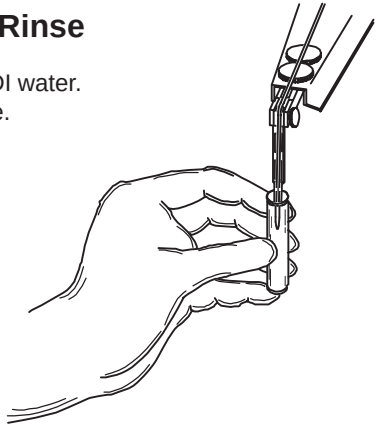


2 Wash Probe

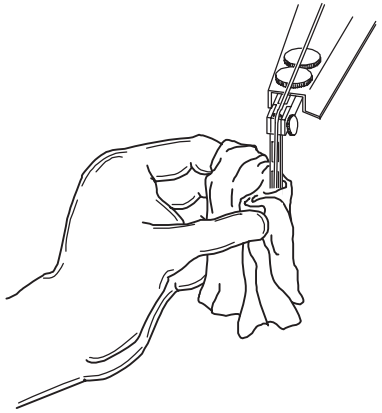


3 Swirl To Rinse

Fill a cuvette with DI water.
Do not bump probe.



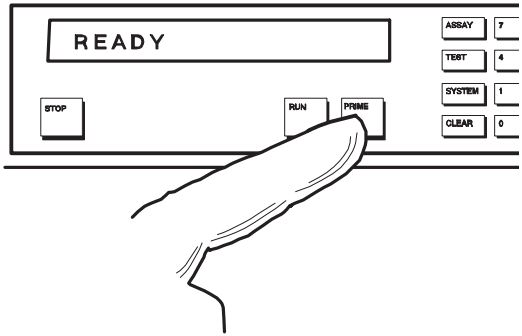
4 Dry



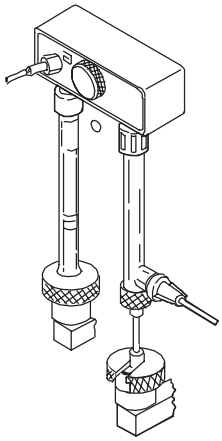
DAILY

5 Prime

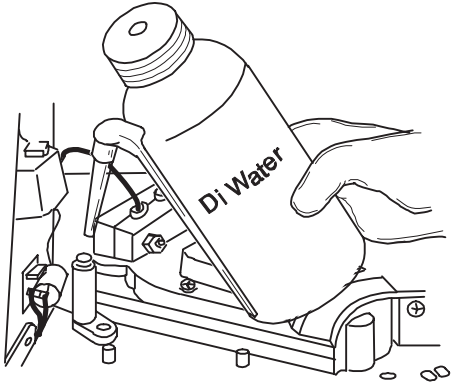
Press **PRIME** key 3 times.



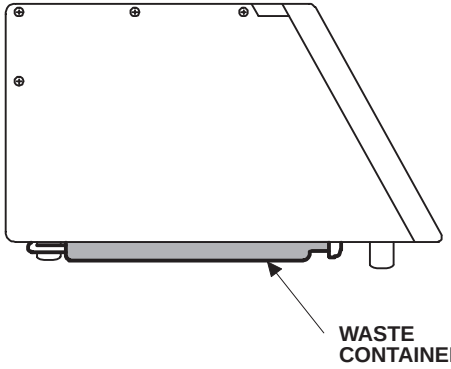
6 Inspect Valve Block/Syringes



7 Clean Waste/Wash Station



8 Empty Waste Container



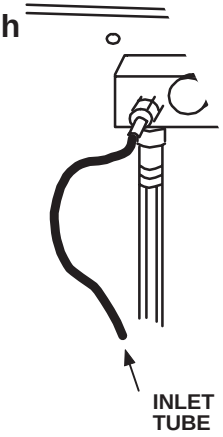
WEEKLY

1 Photo Check

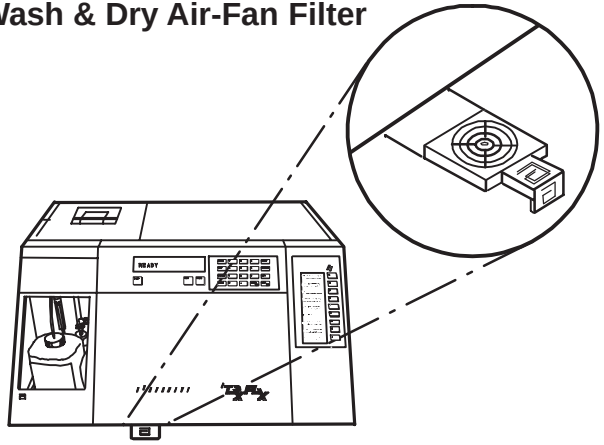
- Remove Fluorometric Standards Function Test Set from storage container, lock and place into analyzer.
- Close door.
- Press **RUN** or **TEST 2.2 RUN**.
- Record results.

2 Perform Dispense Water Wash

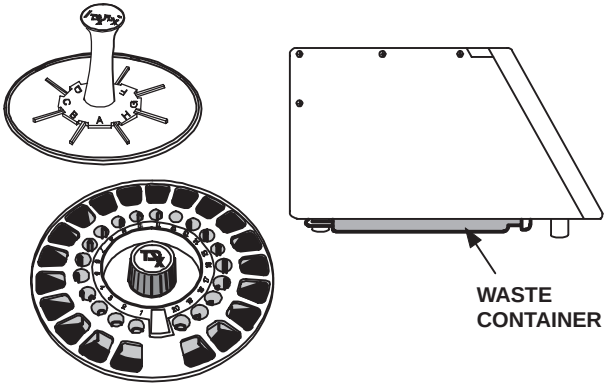
- Place inlet tube into distilled or deionized water reservoir. Prime 5 times.
- Place inlet tube into the buffer container. Prime 5 times.



3 Wash & Dry Air-Fan Filter



4 Wash Waste Container & Carousels



MONTHLY

1 Pipet Check

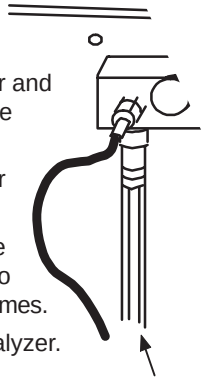
- Select sample carousel.
- Insert 20 sample cartridges and cuvettes into carousel. Lock cuvettes into place.
- Invert pipe check solution 2–3 times to mix. Pipette minimum of 75 µL pipe check solution into sample wells in sample cartridges.
- Lock carousel and place into analyzer. Close door.
- Press **TEST 2.3 RUN**. Do not terminate test with **STOP** key or open access door until display returns to READY.
- Record results.

2 Temperature Check

- Place 20 empty cuvettes into carousel. Lock cuvettes into place.
- Place carousel into analyzer. Close door.
- Press **TEST 2.1 RUN**.
- Record results.

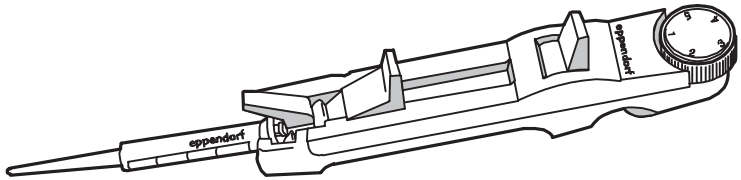
3 ✱Diluent Syringe Wash

- Remove the diluent syringe from the analyzer and pull the plunger out of the inside of the syringe barrel.
- Moisten a lint-free tissue with deionized water and wipe the white tip of the plunger.
- Place a finger over the LUER-LOK® end of the syringe and fill the barrel with deionized water to rinse out the interior. Repeat this step several times.
- Assemble the syringe and replace on the analyzer.



✱ Refer to TDxFLx® System Operations Manual

4 ✱Check Accuracy of Precision Dispenser



✱ Refer to TDxFLx® System Operations Manual

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