

INDEX INSTRUMENT SERVICE ADVISORY

PRODUCT:	DATE:
TDx® (09)	07-JUL-98

ISA#	SUBJECT	EFFECTIVITY DATE
09-114	TDx® Service Manual	07-JUL-98
09-113	TDx® Patent Label (Catalog Number 3-47642-01)	PENDING
09-112	BARCODE ALIGNMENT FLOWCHART	28-JUN-95
09-111	TDx®/TDxFLx® DT MANUAL	07-FEB-95
09-110	NOVRAM COPIER TOOL	11-JAN-94
09-109	PENDING	PENDING
09-108	MOTOR BOARD DIAGNOSTIC TEST (TEST 5.7)	02-JUL-93
09-107	RS232 PORT AND REV. 15.0	17-AUG-93
09-106	ONEAC LINE CONDITIONER	20-AUG-93
09-105A	FPIA OPTICS DIAGNOSTIC PROCEDURE	26-JAN-93
09-104	RIBBON POST AND CARD CAGE FAN	17-AUG-93
09-103	METAL OPTICS ASSEMBLIES	20-APR-92
09-102	PUMP ASSEMBLY IMPROVEMENTS	CLOSED
09-101	POWER ENTRY ASSEMBLY	03-DEC-91
09-100	PRINTER WIRING CRIMPS	08-NOV-91
09-099	PENDING	PENDING
09-098	NEW FACTORY SET PASSWORD	08-NOV-91
09-097	PROBE HOLDER KIT	13-MAR-92
09-096	TUBING	18-JAN-91
09-095	STEPPER MOTORS	18-JAN-91
09-094	FLUOROMETRIC STANDARDS CAROUSEL	26-NOV-90
09-093	NEW STYLE AIR HEATER FAN AND CABLE	07-SEP-90
09-092	LIGHTWEIGHT SAMPLE CARTRIDGES	22-MAY-90
09-091	MULTICONSTITUENT CONTROLS	22-MAY-90
09-090	NEW THUMBSCREWS / LLS TIPS	CLOSED
09-089A	BOOM / REAGENT PACK FIT	CLOSED
09-088	DIGOXIN NXT SYSTEM LOCKUP	CLOSED
09-087	ERRATIC RESULTS TROUBLESHOOTING	INCORP.

TDx® (09) Ir	ndex	
09-086	PROBE AND ELECTRODE ASSEMBLIES	18-AUG-89
09-085	PUMP ASSEMBLIES	26-MAY-89
09-084	METAL BOOM VS -103 PLASTIC BASEPLATES	01-FEB-89
09-083	DATATRAC - SCREWLOCKS AND STATIC TOUCH PADS	15-DEC-88
09-083	PUMP SET SCREWS	CLOSED
09-082	CAROUSEL HOME SENSOR	14-NOV-88
09-080		14-NOV-88
	DOOR GROUND STRAP UPDATE	
09-079C	TDx RETURN INSTRUCTIONS LAMP HOUSING LENSES	18-AUG-93
09-078		INCORP.
09-077	TURBO CAROUSEL PROBLEMS	INCORP.
09-076	NEW STAINLESS STEEL PROBE	CLOSED
09-075	POLYCARBONATE BASE	24-JUL-87
09-074	PHOTO CHECK SPECS	02-JUN-87
09-073	NEW SAMPLE SYRINGE	CLOSED
09-072	IRON SPLASHING	CLOSED
09-071	BUN ELEVATED RESULTS	CLOSED
09-070	TEMPERATURE TIPS	12-SEP-86
09-069	NEW OPTICAL SENSOR	02-SEP-86
09-068	NEW TDx DILUENT SYRINGE	CLOSED
09-067	UNIT DOSE PARAMETERS	INCORP.
09-066	REV 10 REPLACEMENT	CLOSED
09-065	REV 10 & T-UPTAKE ASSAY	CLOSED
09-064	NEW LIQUID HEATER ASSEMBLY	CLOSED
09-063	PLASTIC OPTICS ASSEMBLY	CLOSED
09-062	HIGH VOLTAGE SUPPLY	CLOSED
09-061	CUVETTE BREAKAGE	CLOSED
09-060	NO AIR SPACE PROBLEMS	INCORP.
09-059K	Assays to Activate After FActory Set for TDx® and TDxFLx® Analyzers	09-FEB-96
09-058A	TEMP. VERIFICATION	INCORP.
09-057	NOVRAM DESCRIPTIONS/FACTORY SET INFORMATION	INCORP.
09-056	TEMP SPEC FAILURES	CLOSED
09-055	NEW DIG II ASSAY INFORMATION	CLOSED
09-054	LLS PROBLEMS WITH U.D. PROBE	09-DEC-85
09-053	REA IRON/TIBC ASSAY INFORMATION	CLOSED
09-052	U/D CAROUSEL WEIGHT	CLOSED
09-051	BARCODE READER ADJUST	INCORP.
09-050	CURVE FIT MESSAGES	CLOSED
09-049	TDx PROBES	CLOSED
09-048	LIQUID LEVEL SENSING PROBLEMS	CLOSED
09-047	LCD SWITCHING PROBLEMS	CLOSED
09-046	VALVE HELPS	CLOSED
09-045	TEMP. CKVERIFICATION	INCORP.
09-044	GENERAL INFORMATION	CLOSED
09-043	BD. 12 MODIFICATION	CLOSED

1Dx® (09) Ind		
09-042	UPDATE TO TEMPERATURE CALIBRATION & CK. PROCEDURES	
09-041	HOME SENSOR WIRING	06-SEP-84
09-040	REPLACEMENT OF MEMORY CARTRIDGE & CPU BD	CLOSED
09-039	NEW TEMPERATURE PROBE & TEMP. CAL.	CLOSED
09-038A	NEW LAMPS - SYLVANIA	CLOSED
09-037	LIQ XTAL FAIL - BD. #10	INCORP.
09-036	SHORTING OUT OF DISPLAY BD	04-JUN-84
09-035	REV 8.1 PHOTO CAL.	CLOSED
09-034A	NEW TEMPERATURE PROBE & TEMP. CAL. NEW LAMPS - SYLVANIA LIQ XTAL FAIL - BD. #10 SHORTING OUT OF DISPLAY BD REV 8.1 PHOTO CAL. NO CAROUSEL PROBLEMS	INCORP.
09-033	EFFECTS OF NON-STANDARD CONSUMABLES/PRACTICES	INCORP.
09-032	METHOTREXATE ERRORS IN RESULTS	CLOSED
09-031	THYROXINE LLS ERRORS	CLOSED
09-030	POOR ASSAY PRECISION AND REPRODUCIBILITY	INCORP.
09-029	LAMP OUT AND LOW INTENSITY	INCORP.
09-028	RANGE TOO LARGE - DIGOXIN	INCORP.
09-027	BARCODE LABELS	CLOSED
09-026	VALVE BLOCKS	CLOSED
09-025	ASSAY CAROUSELS	CLOSED
09-024	PACKING OF ASSEMBLIES	CLOSED
09-023	OPTICS ASSEMBLY	INCORP.
09-022	BOOM ASSEMBLY	CLOSED
09-021	PIPE CHECK SOLUTION	CLOSED
09-020	CORRECTION TO ISA 15	CLOSED
09-019	NEW TUBING	CLOSED
09-018	SOFTWARE UPDATES	CLOSED
09-017	NEW CPU	CLOSED
09-016	SYRINGES	INCORP.
09-015	PROBE OPTIMIZATION	CLOSED
09-014	LAMP OUT ERRORS	INCORP.
09-013	MEMORY BOARD	CLOSED
09-012	PRINTER/PRINTER DRIVER	29-JUL-83
09-011	PUMP ASSEMBLY	CLOSED
09-010	BARCODE READER ERRORS	CLOSED
09-009	NEW POWER ENTRY	CLOSED
09-008	METHOTREXATE ERRORS IN RESULTS THYROXINE LLS ERRORS POOR ASSAY PRECISION AND REPRODUCIBILITY LAMP OUT AND LOW INTENSITY RANGE TOO LARGE - DIGOXIN BARCODE LABELS VALVE BLOCKS ASSAY CAROUSELS PACKING OF ASSEMBLIES OPTICS ASSEMBLY BOOM ASSEMBLY PIPE CHECK SOLUTION CORRECTION TO ISA 15 NEW TUBING SOFTWARE UPDATES NEW CPU SYRINGES PROBE OPTIMIZATION LAMP OUT ERRORS MEMORY BOARD PRINTER/PRINTER DRIVER PUMP ASSEMBLY DISPLAY/KEYPAD PROBLEMS LOOSE SCREWS ON TRANSISTORS REV. F SOFTWARE CHANGES MANUAL Z-BOOM HOME CAL. ERRORS IN REV. E SOFTWARE USE OF FLUOROMETRIC STANDARDS CAROUSEL	CLOSED
09-007	LOOSE SCREWS ON TRANSISTORS	CLOSED
09-006	REV. F SOFTWARE CHANGES	CLOSED
09-005	MANUAL Z-BOOM HOME CAL.	CLOSED
09-004	ERRORS IN REV. E SOFTWARE	CLOSED
09-003	ERRORS IN REV. E SOFTWARE USE OF FLUOROMETRIC STANDARDS CAROUSEL MEMORY BOARD REPLACEMENT	CLOSED
09-002	MEMORY BOARD REPLACEMENT	CLOSED
09-001	LIQUID HEATER REPLACEMENT	CLOSED

TDx® (09) Index

PENDING - ISA index number has been reserved for a future ISA.

CANCELLED - ISA index number is cancelled.

INCORPORATED - ISA was incorporated into another document or manual.

OBSOLETE - ISA no longer applies.
COMPLETE - ISA is complete.



INSTRUMENT SERVICE ADVISORY

SUBJECT: TDx® Service Manual	ISA#: 09-114
ORIGINATOR: Eric Tormos	PRODUCT: TDx® (09)
APPROVED: Jack B. Hall 7/7/98	EFFECTIVITY DATE: 07-JUL-98

TDx® is a registered trademark of Abbott Laboratories.

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

This ISA is to notify the field of a revised TDx® Analyzers Total Service Call Procedure. This procedure has been developed from customer site visits made to correct various customer issues. The purpose of this new procedure is to reduce the number of preventive maintenance procedure requirements, while continuing to maintain optimum performance of the instrument.

The Total Service Call Procedure makes sure that the three major subsystems, i.e., temperature, photo and dispense, are checked. Solving an error on one of the subsystems should result in checking the other two as well.

III. PARTS:

None.

IV. PROCEDURE:

6.1 PM/TOTAL SERVICE CALL PROCEDURE

Suggested PM/Total Service Call Procedures

- 1. Verify proper TSB level.
- 2. Obtain printout of System Parameters 1, 2, 3, 6, 7 and 9.
- 3. Wipe analyzer base and cover with 95% ethanol or methanol.
- 4. Clean and inspect optics and lamp housing with compressed air.
- 5. Remove boom assembly.

- Remove air duct cover, clean dust form heater coils and thermistor with compressed air or vacuum cleaner.
- 7. Reinstall boom assembly and perform necessary boom verification procedures as per TDx/TDxFLx Service Manual pages 4-9.
- 8. Prime buffer 5 times and inspect instrument and accessories for leaks in tubing or multivalve block.
- 9. Run boom calibration (only if it ws not yet requested as a verification procedure).
- 10. Run temperature check (only if it was not yet requested as a verification procedure).
- 11. Run photo check (only if it was not yet requested as a verification procedure).
- 12. Run pipe check (only if it was not yet requested as a verification procedure).
- 13. Run assay of customer's choice with controls.
- 14. Obtain printout of System Parameters 1, 2, 3, 6, 7, 9, 10 and 11.

6.2 PM/TOTAL SERVICE CALL CHECKLIST

Suggested PM/Total Call Procedures Performed

1.	Verify proper TSB level.	
2.	Obtain printout of System Parameters 1, 2, 3, 6, 7 and 9.	
3.	Wipe analyzer base and cover with 95% ethanol or methanol.	
4.	Clean and inspect optics and lamp housing with compressed air.	
5.	Remove boom assembly.	
6.	Remove air duct cover, clean dust from heater coils and thermistor with compressed air or vacuum cleaner.	
7.	Reinstall boom assembly and perform necessary boom verification procedures as per TDx/TDxFLx Service Manual pages 4-9.	
8.	Prime buffer 5 times and inspect instrument and accessories for leaks in tubing or multivalve block.	
9.	Run boom calibration (only if it ws not yet requested as a verification procedure).	
10.	Run temperature check (only, if it was not yet requested as a verification procedure).	
11.	1. Run photo check (only if it was not yet requested as a verification procedure).	
12.	Run pipe check (only if it was not yet requested as a verification procedure).	
13.	Run an assay of the customer's choice with controls.	
14.	Obtain printout of System Parameters 1, 2, 3, 6, 7, 9, 10 and 11.	



ABBOTT ADD

INSTRUMENT SERVICE ADVISORY

SUBJECT: Barcode Alignment Flowchart	ISA#: 09-112
ORIGINATOR: Michael A. Mowen	PRODUCT: TDx® (09)
APPROVED: Bob Schabel 28/June/95	EFFECTIVITY DATE: 28-JUN-95

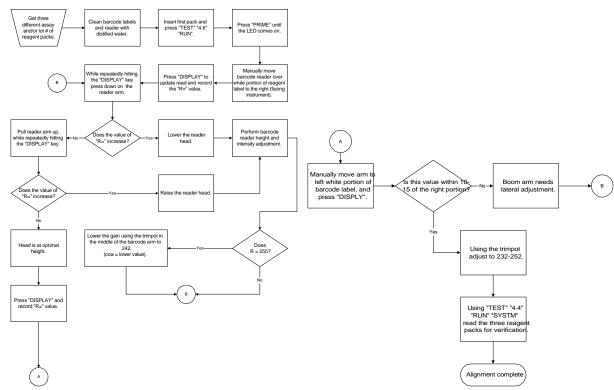
TDx is a registered trademark of Abbott Laboratories.

I. DISTRIBUTION:

International and USA

II. PURPOSE:

To provide the field with a guide to adjust the barcode reader for proper operation, and to save time and repeat calls.



END OF DOCUMENT



ABBOTT ADD

INSTRUMENT SERVICE ADVISORY

SUBJECT: TDx®/TDxFLx® DT MANUAL	ISA#: 09-111
ORIGINATOR: Michael A. Mowen	PRODUCT: TDx® (09)
APPROVED: Bob Schabel 02/08/95	EFFECTIVITY DATE: 07-FEB-95

TDx and TDxFLx are registered trademarks of Abbott Laboratories.

I. DISTRIBUTION:

United States: If a new manual is needed, it can be ordered via a FieldWatch message to Field Service Logistics. The cost of

the manual will be charged to the district's department number.

International: International locations should forecast requirements for the manual to their responsible logistics organization.

II. PARTS:

To order the complete TDx®/TDxFLx® DT-size manual use the following number:

3-45331-02 Complete manual (binders both volume one and two, tabs, text)

This manual replaces the previously released manual for the TDx®/TDxFLx® System, 3-45331-01.

III. PURPOSE:

The New TDx®/TDxFLx® DT-size Service Manual is now available.

IMPROVEMENTS:

The manual is now in the small binder format and updates the previous manual to include TDxFLx Rev. 2.0/2.1, the digital centrifuge, thermal printer, VDE information, and other new information. Volume One corresponds to the IMx® DT service manual, but with text based troubleshooting only. Volume Two contains the reference material, such as the schematics, theory, RS232 specifications, etc. Feedback from FSE/FSRs, has prompted the binders to have locking rings and Mylar reinforced holes, on all pages.

The following TSBs and ISAs were incorporated into the text as follows:

•	TSBs	
	<u>TDx</u> 09-039 09-037B 09-035	TDx REV. 15.1 Software Lamp Socket Assembly TDx REV 15.0 Software
	TDxFLx 67-011 67-009 67-008B 67-007 67-005 67-002A	TDxFLx REV. 2.1 Software TDxFLx REV. 2.0 Software Lamp Socket Assembly Thermal Printer VDE Instrumentation Improved Waste Container Sensor
	ISAs TDx 09-110 09-108 09-107 09-106 09-105A 09-104 09-098	NOVRAM Copier Tool Motor Board Diagnostic Test (Test 5.7) RS232 Port and REV. 15.0 ONEAC Line Conditioner FPIA Optics Diagnostics Procedure Ribbon Post and Card Cage Fan New Factory Set Password
	TDxFLx 67-020 67-018 67-016 67-015 67-014A 67-013 67-010	NOVRAM Copier Tool PCB Retainer Brackets Wash Station Alignment ONEAC Line Conditioner FPIA Optics Diagnostics Procedure Thermal Printer Upgrade MTBF Counter



ABBOTT ADD

INSTRUMENT SERVICE ADVISORY

SUBJECT: MOTOR BOARD DIAGNOSTIC TEST (TEST 5.7)	ISA#: 09-108
ORIGINATOR: Harry Durstine	PRODUCT: TDx® (09)
APPROVED: Bob Schabel 7/2/93 (signature on file)	EFFECTIVITY DATE: 02-JUL-93

TDx is a registered trademark of Abbott Laboratories.

I. PURPOSE:

To inform the field of a potentially false LLS Fail error during the Motor Diagnostic Test (Test 5.7) using ABBOTT TDx® Revision 15.0 software.

II. DESCRIPTION:

During the Motor Diagnostic Test 5.7, a LLS Fail error will occur if Test 5.7 is performed after power up and prior to running as assay. In order to ensure proper functioning of the level sensing portion of Test 5.7, an assay run should be initiated (at least to the point of cuvette count.)

Initially during power up, RGTBOT (System parameter 3.19) and ram location POT3MX are set to zero. When power up is complete, the value of RGTBOT is loaded from NOVRAM. However, ram location POT3MX is not loaded from NOVRAM and remains zero. Ram location POT3MX will be initialized with "RGTBOT" when an assay run is initiated.



INSTRUMENT SERVICE ADVISORY

SUBJECT: ONEAC® Line Conditioner available on RZZ for TDx® System	ISA#: 09-106
ORIGINATOR: Ron Elston/Louis Valich	PRODUCT: TDx® (09)
APPROVED: Bob Schabel 8/13/93 (signature on file)	EFFECTIVITY DATE: 13-AUG-93

TDx is a registered trademark of Abbott Laboratories.

ONEAC is a registered trademark of ONEAC Corporation, Bannockburn, IL.

This ISA is to inform the FSE in the USA that the ONEAC Line Conditioner can now be ordered by the FSE through Dallas Parts and invoiced to the customer. The following is the list number.

Product Code	List Number	Spec: Amps/Volts	ONEAC Model #
09	4A55-37	4.6A/120V	CP1105
67	4A55-39	6.25A/120V	CP1107

I will also give you information about Uninterruptible Power Supplies. These CAN NOT be ordered through or Dallas Parts. The customer will need to contact the ONEAC Corporation directly. For pricing information or to order call:

Product Code	List Number	Spec: Amps/Volts	ONEAC Model #		
09	N/A	5.0A/120V	ON900		
67	N/A	7.5A/120V	ON1300		



INSTRUMENT SERVICE ADVISORY

SUBJECT: Assays to Activate After Factory Set for TDx® and TDxFLx® Analyzers	ISA#: 09-059K
ORIGINATOR: Kyle Hranitzky	PRODUCT: TDx® (09)
APPROVED: Mark Slater 2/9/96	EFFECTIVITY DATE: 09-FEB-96

TDx and TDxFLx are registered trademarks of Abbott Laboratories.

I. DISTRIBUTION:

International and USA

II. PURPOSE:

This ISA supersedes ISA 09-059J dated 18 April 1994.

The purpose of this ISA is to inform the field of the assays needing activation after performing a Factory Set. This ISA will be updated on an as needed basis dependent upon when new assay activation letters are released. If the instrument you are working on has a checksum error, you MUST first bypass the checksum error by inputting the password 955251. Once the checksum error is bypassed a Factory Set Test 6.2 **must** be performed. The password for Test 6.2 Factory Set is 247. This ISA supports TDx® software version 15.0 and 15.1 and TDxFLx® software version 2.0 and 2.1. For activations for older software versions, please contact CSC.

After the Factory Set has passed, the following steps must be performed:

1. Re-enter System 2,3,6,7,8 and 10 parameters and perform Pipe Check Test 2.3 (VP-49).

If these parameters are not available you must perform the following procedures:

TDx and TDxFLx Analyzers

- 1. CRSL CAL (Test 3.3, VP-32)*
- 2. a. BOOM CAL (Test 3.2, VP-31)
 - b. Automated Probe Positioning and Boom Cal (Test 3.10, VP-39) TDxFLx only
- 3. 4-POT BOOM CAL (Test 3.7, VP-35)
- 4. TEMP CAL (Test 3.1, VP-30) and Verification (VP-30)

- PHOTO CAL (Test 3.4, VP-33)
 - 6. PHOTO CHECK (Test 2.2, VP-48)
 - 7. PIPE CHECK (Test 2.3, VP-49)
 - In addition for TDxFLx® Analyzers:

Acetaminophen

- 8. Reagent Carousel Calibration (Test 3.13, VP-36)
- 9. Reagent Wedge Z-Boom Calibration (VP-38)

FLM II

- 10. Barcode Reader DAC Setting (VP-37)
- 11. Waste/Wash Station Alignment (VP-24)

NOTE: Tests and VP's can be found in the TDx®/TDxFLx® Service Manual, Catalog No 3-45331-02.

NOTE: If NOVRAMs were replaced, assays specific to that NOVRAM must be recalibrated (reference TDx/TDxFLx Service Manual pp 4-20 and 4-21, Catalog No 3-45331-02).

The following assays have new activation codes due to reagent pool changes or may have parameters that need to be edited following a factory set.

Phenobarbital

Amikacin Free Carbamazepine Phenytoin Barbiturates II U Free Phenytoin Primidone Benzodiazepines U Free Phenytoin II Procainamide Cannabinoids Gentamicin Propoxyphene Carbamazepine Lidocaine Quinidine T4 Cyclo Meta (WHB) MEGX Theophylline or Theophylline Mono II (LN 8A53) Cyclo Mono (WHB) Methadone Cyclo Meta (P/S) Methotrexate II (LN 7A12) Tobramycin Tricyclic Antidepressants Digitoxin NAPA Valproic Acid Digoxin II Opiates Ethosuximide PCP II Vancomycin

ISA# 09-059K	ISA# 09-059K - Assays to Activate After Factory Set for TDx® and TDxFLx® Analyzers										
Assay # ACET (30)	Date	Batch Lot #	RA Lot#	TDx Codes	TDxFLx Codes	MN POL A	MN SPAN				
, ,	2/94	85944Q100		SYSTEM 5.1 52602073326554	SYSTEM 5.1 52602073326554	225	110				
	3/95	03322Q100		SYSTEM 5.1 62602063326952	SYSTEM 5.1 62602063326952	205	80				
AMIK (3)											
	6/94	88562Q100	88563Q100	SYSTEM 5.1 50602160333533 SYSTEM 5.2 #1 1711150401405 #2 5956044303052 #3 7573511223527	SYSTEM 5.1 50602160333533	203	118				
	2/95	02334Q100	02342Q100	SYSTEM 5.1 20602160333503	SYSTEM 5.1 20602160333503	200	122				

SYSTEM 5.2

#1 1911130203607 #2 9856064304085 #3 4533511264721

0

ISA# 09-059K - Assays to Activate After Factory Set for TDx® and TDxFLx® Analyzers

Assay # BARBS II	Date J (58)	Batch Lot #	RA Lot#	TDx Codes	TDxFLx Codes	MN POL A	MN SPAN
	9/94	92663Q100	Edit Mi	N SPAN		150 BKG FAC 1.24	55
BENZ U (6	3)						
`	9/94	93642Q100		SYSTEM 5.1 48401187217799	SYSTEM 5.1 48401187217799	189 BKG FAC 3.02	122
	2/95	05250Q100		SYSTEM 5.1 13402137267754	SYSTEM 5.1 13402137267754	185 BKG FAC 3.02	108
CANNABS	(60)						
	11/93	85609Q100		SYSTEM 5.1 04401147244009	SYSTEM 5.1 04401147244009	150 BKG FAC 0.73	60
CARB (9)							
,,	12/93	84215Q100	84221Q100	SYSTEM 5.1 75403151241551 SYSTEM 5.2 #1 1312131207618 #2 0359405519089 #3 0552511852822	SYSTEM 5.1 75403151241551	275	140

ISA	Assay # CYCLO MET CYCLO MON	Date A (WHB IO (WHE	ys to Activate Batch Lot #) (18) - Refer to 3) (50) - Refer to 23) - Refer to	RA Lot # Assay Insert Assay Insert	ory Set for TDx® and TDx Codes	J TDxFLx® Analyz TDxFLx Codes	ZERS MN POL A	MN SPAN
	Assay # DIGITOXIN (Date 27)	Batch Lot #	RA Lot#	TDx Codes	TDxFLx Codes	MN POL A	MN SPAN
	,	9/93	80274Q100		SYSTEM 5.1 74001083513255	SYSTEM 5.1 74001083513255	145	72
	DIGOXIN II	(10)						
		10/94	94031Q100		SYSTEM 5.1 31001041512756 SYSTEM 5.2 0 #1 1511132505510 #2 0557025516088 #3 6541511550025	SYSTEM 5.1 31001041512756	155	75

SYSTEM 5.1 42602053360809 SYSTEM 5.1 42602053360809 230

110

ETHOSUXIMIDE (24) 1/94 85534Q100

ISA# 09-059K - Assays to Activate After Factory Set for TDx® and TDxFLx® Analyzers Assay # Date Batch Lot # RA Lot# **TDx Codes** TDxFLx Codes MN POL A MN SPAN FLM II (LN 7A76) (88) **NEW ASSAY** SYSTEM 5.1 SYSTEM 5.1 300 125 60403063290009 60403063290009 SPL VOL =150 HI LIM=160 CAL VOL=150 CONC B=10 CONC C=20 CONC D=40 CONC E=80 CONC F=160 MODE =23 GAIN=20 MX BKG=8000 Pipette 250 uL into the sample well Low control 22-28 mg/g Mid control 44-56 mg/g High control 85-115 mg/g ERR=2 RMSE=1 FREE CARB (32) 12/93 84215Q100 SYSTEM 5.1 SYSTEM 5.1 275 120 83403144250552 83403144250552 5/95 120 03189Q100 32403124240551 32403124240551 275 FREE PHENY (LN 9530) (26) 89400Q100 SYSTEM 5.1 233 130 5/94 SYSTEM 5.1 40402143262839 40402143262839 12/94 95130Q100 SYSTEM 5.1 SYSTEM 5.1 250 140 40403143262801 40403143262801

SYSTEM 5.1

CONC C=1

00403143262852

CONC D=2

265

CONC F=4

SYSTEM 5.1

CONC E=3

00403143262852

125

FREE PHENY II (LN1B62) (26) NEW ASSAY

CONC B=0.5

5/95

SPL VOL=10

Assay # GENT (1)	Date	Batch Lot #	RA Lot #	TDx Codes	TDxFLx Codes	MN POL A	MN SPAN
,	6/94	89465Q100	89466Q100	SYSTEM 5.1 70401140211058 SYSTEM 5.2 0 #1 1611241205609 #2 0403014401087 #3 0542511141923	SYSTEM 5.1 70401140211058	175	90
LIDOCAINE	(14)						
	4/94	88586Q100	88587Q100	SYSTEM 5.1 33402131276059 SYSTEM 5.2 0 #1 1611252404815 #2 5206175422028 #3 8562511951520	SYSTEM 5.1 33402131276059	225	120
MEGX (78)							
	9/92	69771M200		SYSTEM 5.1 77001161566059	SYSTEM 5.1 77001161566059	135	55

Edit CAL REP to 2

METHADONE (48)

Edit BKG FAC to 2.23

ISA# 09-059K - Assays to Activate After Factory Set for TDx® and TDxFLx® Analyzers

Assay #	Date	•	RA Lot#	TDx Codes	TDxFLx Codes	•	MN SPAN
•		LN 7A12) (22) NI		15.1 Only	2.1 Only	027	01 7.11
	10/93	,, (, ,		SYSTEM 5.1 24002442566504	SYSTEM 5.1 24002442566504	180	120
_	VOL=10	HI LIM=1000	CONC B=0.0		CONC D=0.30	CONC E=0.60 C	ONC F=1.00
MOL	DE 42	GAIN 40	MX BKG 250	U			
NAPA (13))						
	6/94	91508Q100	91509Q100	SYSTEM 5.1 53602121365556 #1 1712010102511 #2 0859465516085 #3 6571511723121	SYSTEM 5.2 53602121365556	205	125
OPIATES	(62)						
	11/92	71678Q100		SYSTEM 5.1 38401137206407	SYSTEM 5.1 38401137206407	170 BKG FAC 1.3	90 36
PCP II (61	4/94	87066Q200		SYSTEM 5.1 94401127255558	SYSTEM 5.1 94401127255558	135 BKG FAC 0.8	80 38

Assay # PHENOBAR	Date B II (05)	Batch Lot #	RA Lot#	TDx Codes	TDxFLx Codes	MN POL A	MN SPAN
	5/92	67313Q100	67314Q100	SYSTEM 5.1 44402090295207 SYSTEM 5.2 0 #1 1411241204909 #2 0407144418049 #3 9562511641927	SYSTEM 5.1 44402090295207	180	115
	3/94	87088Q100	87087Q100	SYSTEM 5.1 03402080285206 SYSTEM 5.2 #1 1411241404901 #2 5803175413027 #3 1553511212123	SYSTEM 5.1 03402080285206	180	125
PHENYTOIN	(LN950	07)(4)					
	5/94	89400Q100	89405Q100	SYSTEM 5.1 10402140244857 SYSTEM 5.2 0 #1 1012322106019 #2 5052235514006 #3 9573511042920	SYSTEM 5.1 10402140244857	235	135

Assay #	Date	Batch Lot #	RA Lot#	TDx Codes	TDxFLx Codes	MN POL A	MN SPAN
PHENYTOI	N (LN 950	07) (4) CONTINUI	ED				
	12/94	95130Q100	95131Q100	SYSTEM 5.1 20402140244858 SYSTEM 5.2 #1 1712272605902 #2 5053255311039 #3 7522511852222	SYSTEM 5.1 20402140244858	245	145
PHENYTOI	N II (LN 1	B61) (4)					
	5/95	NEW ASSAY		SYSTEM 5.1 80403140244880 SYSTEM 5.2 #1 000000008211 #2 00000000862 #3 9500500000120	SYSTEM 5.1	268	168
SPL	VOL=2	CONC B=2.5	CONC C=5		CONC E=20	CONC F=40	
PRIMIDONI	≣ (6)						
	7/93	79423Q100	79415Q100	SYSTEM 5.1 94602150306552 #1 1711211003906 #2 0901245519048 #3 5552511821629	SYSTEM 5.1 94602150306552	225	120

Page 25

ISA# 09-059K - Assays to Activate After Factory Set for TDx® and TDxFLx® Analyzers

Assay # PRIMIDONE	Date (6) CON		RA Lot#	TDx Codes	TDxFLx Codes	MN POL A	MN SPAN
	8/94	91482Q100	91490Q100	SYSTEM 5.1 30602110366558 SYSTEM 5.2 0 #1 1511230208418 #2 0809255519004 #3 7552511641829	SYSTEM 5.1 30602110366558	225	120
PROCAINAN	IIDE (12)						
	1/94	85475Q100	85476Q100	SYSTEM 5.1 40002071524003 SYSTEM 5.2 0 #1 1711131307915 #2 5854274416042 #3 8551511852522	SYSTEM 5.1 40002071524003	210	115
	6/94	90636Q100	90682Q100	SYSTEM 5.1 41002081534073 #1 9199090902413 #2 6131095418053 #3 3590599190321	SYSTEM 5.1 41002081534073	207	115

Page 26

Assay # Date	Batch Lot #	RA Lot#	TDx Codes	TDxFLx Codes	MN PC	DLA MN SPA
PROPOXYPHENE (8 10/91	NEW ASSAY	•	SYSTEM 5.1 66402112281108	SYSTEM 5.1 66402112281108	200	115
SPL VOL=3.2 MODE=26	HI LIM=300 GAIN=20	CONC B=150 MX BKG=2500		D=500 CONC E=1	000 (CONC F=1500
QUINIDINE (11)						
1/93	74213Q100	73403Q101	SYSTEM 5.1 36402221273004 SYSTEM 5.2 0 #1 1511272403411 #2 0503025516032 #3 6531511650126	SYSTEM 5.1 36402221273004	170	85
T4 (79)		Edit Mi	N SPAN			100
THEOPHYLLINE II (15)					
6/93	78596Q100	78598Q100	SYSTEM 5.1 46002151517006	SYSTEM 5.1 46002151517006	250	160

SYSTEM 5.2 0 #1 2711303803817 #2 0103265529005 #3 6563511081729

Assay #		Batch Lot #	RA Lot#		TDxFLx C	odes	MN POL	A MN SPAN
THEOPHYLL	INE MO	NOCLONAL II (LN	I 8A53) (15) NE	EW ASSAY SYSTEM 5.1 88002191537507 SYSTEM 5.2 #1 000000007221 #2 000000018061 #3 9500500000120	SYSTEM 5 880021915		240	170
SPL VC MODE:		HI LIM=40 GAIN=40	CONC B=2.5 MX BKG=160	CONC C=5	C D=10	CONC E	=20	CONC F=40
TOBRAMYC	IN (02) 10/92	71007Q100	71008Q100	SYSTEM 5.1 77602210392456 SYSTEM 5.2 (#1 1111220205702 #2 0758064408031 #3 1562511542228	SYSTEM 5 776022103		175	105
TRICYCLICS	8/92	PRESSANTS (56 67529Q100)	SYSTEM 5.1 47002187530001			180	100

ISA# 09-059K - Assays to Activate After Factory Set for TDx® and TDxFLx® Analyzers						
Assay # Date VALPROIC ACID (8)	Batch Lot #	RA Lot#	TDx Codes	TDxFLx Codes	MN POL A	MN SPAN
2/94	87356Q100	86535Q100	SYSTEM 5.1 44002091520704 SYSTEM 5.2 0 #1 1812180606418 #2 0008315515002 #3 8552511041824	SYSTEM 5.1 44002091520704	220	110
VANCOMYCIN (16) 1/94	85096Q100	85097Q100	SYSTEM 5.1 00402092260357 SYSTEM 5.2 #1 1411241505127 #2 5503045428037 #3 4543511831720	SYSTEM 5.1	215	105