

## TRAINING UPDATE

Lab Location:GECDate Distributed:10/2/2012Department:CoreDue Date:10/31/2012

## DESCRIPTION OF PROCEDURE REVISION

Name of procedure:								
Startup and Maintenance, Siemens Dimension® Xpand	GEC.C07.004							
Dimension Xpand Maintenance Log	AG.F179.001							
Sample Processing, Siemens Dimension® Xpand	GEC.C08.002							
Dimension Xpand Limits Chart	AG.F143.002							
Calibration / Verification Siemens Dimension® Xpand	GEC.C11.002							
Xpand Calibration Log	AG.F112.001							

# **Description of change(s):**

**Startup and Maintenance** 

section	description
1 & 2	add analyzer name
	remove instructions specific to SGAH and/or WAH; change IMT System clean,
5	Stylette HM wash probe & Millipore to monthly frequency, add HM pump heads
9	remove RXL log, add Xpand log

**Sample Processing** 

section	description
1 & 2	add analyzer name
9	rename chart, revise to reflect GEC testing only

## **Calibration / Verification**

Cumpiano	n, vermeuton
section	description
1 & 2	add analyzer name
5	delete drugs of abuse calibration, add step for failure to C & D
6	update document titles
9	rename Calibration log, remove RXL drugs of abuse log.

# Changes on SOPs are blue

Document your compliance with this training update by taking the quiz in the MTS system.

Quest Diagnostics Nichols Institute Site: Germantown Emergency Center Title: Startup and Maintenance, Siemens Dimension® Xpand

Non-Technical SOP

Title	Startup and Maintenance, Sier	artup and Maintenance, Siemens Dimension® Xpand						
Prepared by	Leslie Barrett	Date: 8/10/2009						
Owner	Robert SanLuis	Date: 6/8/2011						

Laboratory Approval									
Print Name and Title	Signature	Date							
Refer to the electronic signature page for									
approval and approval dates.									
Local Issue Date:	Local Effective Date:								

12 month (or new) management review and approval: Signature acknowledges SOP version remains in effect with NO revisions.								
Print Name	Signature	Date						

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### Title: Startup and Maintenance, Siemens Dimension® Xpand

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### PURPOSE

To outline the daily startup procedure for the Siemens Dimension Xpand instruments and describe all other maintenance that must be performed as scheduled.

#### 2. SCOPE

This procedure applies to all Core Laboratory personnel working with the Siemens Dimension Xpand instruments.

#### RESPONSIBILITY 3.

Core Laboratory personnel are responsible for performing and complying with this

The Technical Supervisor is responsible for content and review of this procedure.

### DEFINITIONS

None

#### PROCEDURE 5.

## A. General Information and Schedule

- 1. The daily startup, weekly and monthly maintenance will be performed by the night shift.
- 2. The daily monitoring of the instrument waste will be performed on all three shifts.
- 3. The Core Laboratory Group Leads are responsible for the weekly review of maintenance logs.

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- 4. The Core Laboratory Supervisor, Operational Director or designee is responsible for the monthly review of maintenance.
- 5. A check off log is provided on each instrument for the technologist to sign. The required checkpoints must be completed as scheduled. A technologist on each shift must initial that they have completed the required checkpoints.
- 6. Documentation After any maintenance is completed the following must be performed.
  - a. Run System Check. Document results on the forms provided for each instrument.
  - b. Run OC.
  - c. Do not release any patient result until the System check and QC successfully
  - d. Document function check on the maintenance Log Sheet.

### **B.** Daily Startup

- 1. Delete all segments positions
  - a. Press Alt/S
  - b. Press F3 Delete
  - c. Respond to prompts.
- 2. Access the Daily Maintenance Program. From the Operating Menu:
  - a. Press F4: System Prep
  - b. Press F8: Daily Maint
- 3. Record the cuvette and reagent temperatures in the Maintenance Log.
- 4. Clean the sample area and empty cuvette waste
  - a. With the instrument in Standby, press Pause to stop the sampler systems from
  - b. Raise the sample and reagent lids and remove all segments from the sample area.
  - c. Clean the inside of the sample with a damp cloth.
  - d. Close the sample and reagent lids.
  - e. Press Pause to restart the sampler system.
  - f. Open the right cabinet door and cut the cuvette string about 12 inches down from the instrument. Be sure to cut the between two cuvettes to prevent spilling fluids from a sealed cuvette.
  - g. Empty the accumulated cuvette waste.
- 5. Check for other maintenance when F2: Check Counts or F3: HM Counts appears in the function key area, Sample, R1 and R2 probes are to be changed before or at 30,000 cycles.

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#### 6. Run System Check:

- a. Press Alt/I to verify that the ABS reagent cartridge is on the instrument.
- b. When using a new ABS reagent lot, enter the ABS carton value in the method parameters. Press F4 System Prep, Press F8 Daily Maintenance, arrow up to Carton value and enter new carton value located on end of flex box, then F8 Store Changes.
- c. Fill a sample cup with fresh ABS solution. (It MUST be the same lot # as the one on the instrument).
- d. Designate a segment position and load the cup.
- e. Press F1: Start
- 7. Record System Check results in the Maintenance Log.

Unacceptable System Check results appear on the print out in white letters on a black background. An asterisk on the report indicates that the cuvette had a processing problem. If the System Check Printout indicates that your results are not acceptable refer to System Check Trouble shooting in the Operators Guide.

- 8. Check/replenish reagent, IMT and HM inventory:
  - a. For reagent inventory, press Alt/I
  - b. For IMT, from the Operating Menu, press:
    - 1) F4: System Prep
    - 2) F3: IMT
    - 3) F1: Change Consumables
  - c. For HM, from the Operating Menu, press
    - 1) F4: System Prep
    - 2) F6: System Counters
    - 3) F6: HM Counters
- 9. Process Quality Control according to Laboratory procedures.

### C. Weekly Maintenance

- 1. Clean HM Wash Probes and the R2 reagents Probe
  - a. With the system in Stand by, go to the HM Pump Prime screen
  - b. Raise the sample and regent lids.
  - c. Dip a clean cotton swab in water and, beginning at the top of the probe, wipe down the outside of both wash station probes.
  - d. Turn the splined shaft on the R2 reagent arm until the R2 probe comes up out of the R2 reagent drain. Then move the arm until you can easily access the R2
  - e. Dip a clean cotton swab in 0.1N sodium hydroxide and scrub the nut at the top of the probe tube. Then, beginning at the top, wipe down the outside of the R2 reagent probe.
  - f. Press F1: HM Wash Pump to prime the HM wash pump.
  - g. Document the cleaning on the Weekly Log Sheet.

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- Replace IMT Sensor, Run Dilution Check & Condition Sensor.
   (This is done every 5 days and the instrument will give a reminder) For step by step procedure see the IMT Info section in the Dimension Quick Reference Guide or the Operator's Guide 2-59.
- 3. Clean Windows

### D. Monthly Maintenance

- 1. Siemens Dimension
  - a. Replace IMT Pump Tubing
  - b. Replace / Clean Air Filters
  - Replace HM Pump Heads
     For step by step procedure see the Operator's Guide 3-15.
  - d. Stylette the HM Wash Probes
  - e. IMT System Clean (The instrument will give a reminder)
     For step by step procedure see the IMT Info section in the Dimension Quick Reference Guide or the Operator's Guide.

### 2. Millipore

- a. Culture Millipore Water. Clean tip with alcohol pads first. Then pour a 1:10 bleach/water solution over the tip and let sit for a minimum of 15 minutes. Let water flow into the basin until half full and then culture the water.
- Replace Chlorine Tablet as needed by the indicator light on the Millipore.
   Refer to Millipore (AFS Analyzer Feed System) procedure for step-by-step instructions.

### E. Non-scheduled or 'As Needed' Maintenance

Note: not limited to those listed below

- 1. Sample probe change before or at 30,000 cycles.
- 2. Reagent probes (R1 and R2) change before or at 30,000 cycles.
- 3. Source lamp changed
- 4. IMT probe change
- 5. IMT tubing change
- 6. Any scheduled maintenance that is performed off-cycle

### 6. RELATED DOCUMENTS

Millipore (AFS – Analyzer Feed System), Chemistry procedure The Dimension Quick Reference Guide

#### 7. REFERENCES

Dimension Xpand Clinical Chemistry Operators' Guide, 09/2008

Form revised 3/31/0

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## Title: Startup and Maintenance, Siemens Dimension® Xpand

#### REVISION HISTORY

Quest Diagnostics Nichols Institute

Site: Germantown Emergency Center

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP C041.002		
000	2/11/11	Update owner and title page	W.	Dr
		Section 5: item A.8 relocated from end of section, item F added	McMillan	Cacciabeve
001	6/8/11	Update owner Section 5: change Stylette HM wash probes and clean windows to weekly maintenance, remove monthly monopump maintenance Section 9: add maintenance form	L Barrett	Dr Cacciabeve
002	1/29/12	Section 5: Items B.5 and F.1&2 - add frequency for change before or at 30,000 cycles.  Section 9: edit log sheets to reflect cycle count for probe changes.	J Buss	Dr Cacciabeve
003	8/14/12	Sections 1 & 2: add analyzer name Section 5: remove instructions specific to SGAH and/or WAH; change IMT System clean, Stylette HM wash probe & Millipore to monthly frequency, add HM pump heads Section 9: remove RXL log, add Xpand log	L Barrett, A Chini	R SanLuis

### 9. ADDENDA AND APPENDICES

Dimension Xpand Maintenance Log (see Attachment Tab of Infocard)

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## DIMENSION XPAND MAINTENANCE LOG

										S/N									_					MC	NTF	I/YE	AR _					
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Verify Cuvette Temp. (36.8° - 37.2° C)	-			•		Ü	,			10			10		10	10	17	10		20	21		25		20	20		20		50	
LY	Verify Reagent Temp. (2° - 8° C)																															
DAILY	Verify HM Temp. (42° - 44° C)																															
	Verify System Check Cut Waste Film																															
	Record Millipore Readings																															
	Daily QC Performed and Verified By / Include Initials																															
				Dota	e and	Init	iole					Doto	and	Initia	alc				Г	ate a	nd I	nitio	c			•	D	ate ar	nd In	itials	•	
WEEKLY	Clean Outside of R2 and HM Wash Probes			Dau	e and	1 11111	1415				•	Date	anu .	111111	115				L	alt a	iiiu 1	шиа	13				De	ate ai	IU III	itiais		
EE	Clean Windows																															
$\mathbf{X}$		I	Date	and l	nitia	ls		Date	and	Initi	als		Date	e and	l Init	ials		Dat	te an	d Ini	tials		Da	ate ar	ıd In	itials	3	D	ate a	nd In	itials	S
	Replace IMT Sensor Run Dilution Check & Condition Sensor (LOT#)																															
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Y	IMT System Clean																															
	•																															
田	Replace IMT Pump Tubing																															
NTHL	Replace IMT Pump Tubing Replace / Clean Air Filters																															
MONTHL	Replace / Clean Air Filters																															
MONTHLY																																
MONTHL	Replace / Clean Air Filters Replace HM Pump Heads Stylette HM Wash Probes																															
MONTHL	Replace / Clean Air Filters Replace HM Pump Heads Stylette HM Wash Probes Clean Sample Probe & Drain																															
	Replace / Clean Air Filters Replace HM Pump Heads Stylette HM Wash Probes Clean Sample Probe & Drain Replace Sample Probe*																															
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AS NEEDED MONTHL	Replace / Clean Air Filters Replace HM Pump Heads Stylette HM Wash Probes Clean Sample Probe & Drain Replace Sample Probe* Replace R1 Probe* Replace R2 Probe*																															
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	Replace / Clean Air Filters Replace HM Pump Heads Stylette HM Wash Probes  Clean Sample Probe & Drain Replace Sample Probe* Replace R1 Probe* Replace R2 Probe* Change Source Lamp Replace Chlorine Tablet	owing	:																													
AS NEEDED	Replace / Clean Air Filters Replace HM Pump Heads Stylette HM Wash Probes  Clean Sample Probe & Drain Replace Sample Probe* Replace R1 Probe* Replace R2 Probe* Change Source Lamp Replace Chlorine Tablet Verify Calibration for the follow																															
* AS NEEDED	Replace / Clean Air Filters Replace HM Pump Heads Stylette HM Wash Probes  Clean Sample Probe & Drain Replace Sample Probe* Replace R1 Probe* Replace R2 Probe* Change Source Lamp Replace Chlorine Tablet Verify Calibration for the follo CRP (QC± 1.5sd)							Wee	ekly i	revie	w:									We	ekly	revi	ew:									

Quest Diagnostics Nichols Institute Title: Sample Processing, Siemens Dimension® Xpand
Site: Germantown Emergency Center

Non-Technical SOP

Title	Sample Processing, Siemens Dimension® Xpand							
Prepared by	Leslie Barrett	Date: 7/31/2009						
Owner	Jean Buss, Robert SanLuis	Date: 10/27/2011						

Laboratory Approval								
Print Name and Title	Signature	Date						
Refer to the electronic signature page for approval and approval dates.								
Local Issue Date:	Local Effective Date:							

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Print Name	Signature	Date			

OUTITION DISTRICT

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Quest Diagnostics Nichols Institute Title: Sample Processing, Siemens Dimension® Xpand Site: Germantown Emergency Center

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· ·		

### 1. PURPOSE

This procedure outlines the steps for processing a sample on the Siemens Dimension Xpand instruments.

### 2. SCOPE

This procedure applies to all Core Laboratory personnel working with the Siemens Dimension Xpand instruments.

### 3. RESPONSIBILITY

Core Laboratory personnel are responsible for performing and complying with this procedure.

The Technical Supervisor is is responsible for content and review of this procedure.

### 4. **DEFINITIONS**

None

### 5. PROCEDURE

### A. General Information

- 1. If an aliquot or dilution is required, never pour sample back into the primary tube.
- 2. When preparing an aliquot or dilution, only handle one patient sample at a time.
- 3. A straight pour-off into an SSC must be immediately placed into the primary tube.
  - a. If there is specimen left in the primary tube, discard the SSC when testing is complete
  - b. If there is no specimen left in the primary tube, parafilm the top and save.
- 4. If there is limited quantity of a specimen, parafilm and save the sample cup.
- 5. All saved specimens must be labeled with patient identification.
- 6. Never dilute into small sample containers (SSC).

al use only.

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#### B. Processing

#### Bar-coded Tubes

- a. Check for sufficient sample volumes using the tube fill gauge located by the instrument.
- b. Place the bar-coded sample on a black segment in the appropriate adaptor. (5 ml tube –teal, 7 ml tube tan, 10 ml tube no adaptor.)

### 2. Short Samples Bar-coded Tube

- a. Transfer the sample into the clear plastic small sample containers (SSC).
- b. Place SSC atop the bar-coded tube
- Place the tube into an available position in the SSC designated segment (Orange or Yellow).
- d. Ensure the barcode label is visible in the opening of the segment.

#### 3. Non Bar-coded Tube

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SOP version # 002

- a. Label sample cup with patient ID, include dilution if applicable.
- Transfer the samples to a plastic sample cups and place on a black segment in any color adaptor.
- c. Enter patient information manually using the procedure below.

Note: Urine and CSF specimens will be processed in sample cups.

### 4. Manually Entering Patient Information

a. From main operating menu, press F1: Enter Data.

POSITION	Enter segment letter and position number.
PATIENT NAME	Enter name (if applicable).
SAMPLE NO	Enter patient accession number (Manual query can be used by entering * accession number. If the patient is in the LIS, this will fill in the patient information)
LOCATION	Entry optional.(except during downtime)
TEST	Select test by pressing method keys on keyboard.
F7: MODE	Select the sample container you are using. Sample cup primary tube, SSC, etc.
F4: PRIORITY	Select Routine, stat, etc.
DILUTION	Enter dilution factor (if applicable).
F8: FLUID	Select serum, urine, plasma, or CSF.

- b. To run a single specimen, enter the patient information. Place the specimen in the segment position you have selected, press F2: Process Single.
- If you have more than one sample to enter manually, press F1: New Sample after each entry.
- d. After entering all samples, press F3: Load List. Place samples in the designated segment positions, on the load list

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Title: Sample Processing, Siemens Dimension® Xpand

#### C. Loading

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- 1. Loading Sample for Standby Status Mode
  - Ensure that all instrument lids are closed and all instrument doors and panels are closed.
  - b. Ensure that segments have been loaded into the sample wheel.
  - c. Completely seat the correct sample container in the correct segment position.
  - d. Position bar code labels so that the bar code is visible in the opening of the segment.
  - e. Press the run key on the keyboard.

### 2. Adding Samples while running the System in Processing Status

- a. Before adding samples while the system is in processing status, check the segment position in the segment status area of the screen.
- b. If there is no segment letter in that position, you can load a new segment.
- c. If the segment letter has a green background color, you can add new samples to empty or unassigned position of the segment or remove and replace the segment.
- d. If the segment has a red background color you can add new samples to empty or unassigned position of the segment but DO NOT REMOVE the segment or reposition the segment to another position on the sample wheel and DO NOT remove any sample container from the segment.
- e. Press run key on the keyboard.

#### 6. RELATED DOCUMENTS

None

#### 7. REFERENCES

Dimension RXL Max Clinical Chemistry Operators' Guide August 2008 Dimension Xpand Clinical Chemistry Operators' Guide February 2007

### 8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP C051.002		
000	10/27/11	Update owner	L Barrett	J Buss
		Section 5: add part A, labeling requirement added	A Chini	
		to B.3		
		Section 9: update CKI, LIPL, ALT, AST, GGT,		
		LA, HA1C, and UCFP; remove urine Cl and AMY.		
		Location added		
001	8/8/12	Sections 1 & 2: add analyzer name	L Barrett	J Buss,
		Section 9: rename chart, revise to reflect GEC	A Chini	R SanLuis
		testing only		

### 9. ADDENDA AND APPENDICES

Dimension Xpand Limits Chart (see Attachment Tab of Infocard)

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# DIMENSION® XPAND LIMITS CHART

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT
ACTM	μg/mL	2	2.0-600.0	3	2.0-900.0	Drug Calibrator II Level 1, or Acetaminophen Free Serum
ALB	g/dL	2.5	0.6-20.0	3	0.6-24.0	Water
ALC	mg/dL	1.5	0-450	3	5-900	Water
ALP	U/L	2.3	11-2,300	10	11-10,000	Enzyme Diluent
ALT	U/L	7	0-7000	10	0-10,000	Enzyme Diluent
AMY	U/L	2	0-1,300	10	0-6,500	Enzyme Diluent
AST	U/L	8	6-8000	10	6-10,000	Enzyme Diluent
BUN	mg/dL	1.5	0-225	3	0-450	Water
CA	mg/dL	1.7	5.0-25.5	3	5.0-45.0	Water
CKI	U/L	7	7-7000	20	7-20,000	Water
CL	mmol/L	N/A	N/A	N/A	50-200	Do NOT Dilute
CREA	mg/dL	2	0.0-40.0	3	0.0-60.0	Water
CRP	mg/dL	1.5	0.2-18.0	5	0.2-60.0	Water
CTNI	ng/mL	2.5	0.04-100.00	5	0.04-200.00	Water
DBIL	mg/dL	1.9	0.0-38.0	5	0.0-100.0	Water
ECO2	mmol/L	N/A	N/A	2	5-90	Water
GLUC	mg/dL	1.5	0-750	5	0-2,500	Water
HCG	mIU/mL	200	1-200,000	5	1-1,000,000	Sample Diluent
K	mmol/L	N/A	N/A	N/A	1.0-10.0	Do NOT Dilute
LA	mmol/L	2	0.3-30.0	N/A	0.3-30.0	Do NOT Dilute
LIPL	U/L	1.5	10-2250	10	10-15,000	Water
MG	mg/dL	N/A	N/A	3	0.0-60.0	Water
MMB	ng/mL	2	0.5-600.0	5	0.5-1,500.0	Sample Diluent
NA	mmol/L	N/A	N/A	N/A	50-200	Do NOT Dilute
SAL	mg/dL	3	0.2-300.0	3	0.2-300.0	Water
TBIL	mg/dL	2	0.0-50.0	5	0.0-125.0	Water
TP	g/dL	1.9	2.0-22.8	3	2.0-36.0	Water
TSH	μIU/mL	2	0.01-100.00	5	0.01-250.00	Sample Diluent
UCFP (CSF)	mg/dL	2	6-500	10	6-2500	Water

Quest Diagnostics Nichols Institute Site: Germantown Emergency Center Title: Calibration / Verification Siemens Dimension® Xpand

Non-Technical SOP

Title	Calibration / Verification Siemens Dimension® Xpand		
Prepared by	Leslie Barrett	Date: 1/15/2010	
Owner	Robert SanLuis	Date: 5/24/2011	

Laboratory Approval					
Print Name and Title	Signature	Date			
Refer to the electronic signature page for approval and approval dates.					
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Print Name	Signature	Date			

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### Title: Calibration / Verification Siemens Dimension® Xpand

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## 1. PURPOSE

To outline the calibration process for the Siemens Dimension Xpand instruments.

## 2. SCOPE

This procedure applies to all Core Laboratory personnel working with the Siemens Dimension Xpand instruments.

## 3. RESPONSIBILITY

Core Laboratory personnel are responsible for performing and complying with this procedure.

The Technical Supervisor is responsible for content and review of this procedure.

## 4. **DEFINITIONS**

None

### 5. PROCEDURE

## A. Calibration/Verification set up

1. From Operating Menu

Press F5: Process Control

Press F1: Calibration

Enter Password

Press F2: SETUP and RUN

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- Select the test method to be calibrated. If the lot number is incorrect press F1 to toggle to other lot number. If lot number is not there, go to F4 System Prep, F1 Inventory, F1 Show Hold, F1 Replace 3<sup>rd</sup> Lot, Press Yes. Repeat Cal/Ver Set Up.
- 3. Enter all information on screen
- 4. Press F8: QC yes/no to change to yes
- 5. Press F4: Assign cups

If additional methods need to be calibrated, select the method.

- 6. Press F7: Load/run
- 7. Load cups into assigned position
- 8. Press F4: RUN
- Complete the appropriate Calibration Log with all applicable information. Attach calibration tapes and submit for review.

### **B.** Calibration Troubleshooting

This section contains guidelines for troubleshooting a failed calibration:

- Precision Refer to the Dimension Cal Accept Guidelines Form
- Calibration Statistics Refer to the Dimension Cal Accept Guidelines Form
- Quality Control Refer to the Quality Control policy

#### C. Troubleshooting Precision of Calibration Results

- Review calibrator preparation and expiration date on the package insert sheet of the calibrator product. Verify that the storage conditions matched the manufacturer's guidelines.
- Follow the every detail of the manufacturer's guidelines, when preparing lyophilized products.
- Review the instrument maintenance logs and the system counters screen for any
  maintenance that may be overdue. If the problem occurs on a method with a low
  sample volume, check the cycle count for the sample probe tip.
- Check that all temperatures are within range on the Daily Maintenance screen.
  - All temperatures must be verified with a calibrated thermometer, according to the Calibrating Cuvette System Temperature, Calibrating Reagent System Temperature, and Calibrating HM Module Temperature procedures in your operator's guide.
- If any data points are missing due to a process error:
  - o For logic methods, you must reject the calibration
  - For linear methods, up to three data points can be missing as long as there is at least one data point for each level. If the calibration meets these criteria, it can be accepted.

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Site: Germantown Emergency Center

 After troubleshooting, repeat calibration. If results are still found to be unacceptable, notify supervisor or director. Suspend testing until problem is resolved.

## D. Troubleshooting Calibration Statistics

- Ensure that the calibrator insert sheet corresponds with the lot number being calibrated
- Review calibrator preparation and expiration date on the package insert sheet of the calibrator product. Verify that the storage conditions matched the manufacturer's guidelines.
- Follow the every detail of the manufacturer's guidelines, when preparing lyophilized products.
- Check that the sample cups were loaded into the segment in the proper order. If they were not, you must press F8: Reject data and rerun the calibration.
- Review the instrument maintenance logs and the system counters screen for any
  maintenance that may be overdue. If the problem occurs on a method with a low
  sample volume, check the cycle count for the sample probe tip.
- Check the Daily Maintenance screen to ensure that all temperatures are within range. Check the temperatures with a calibrated thermometer according to the Calibrating Cuvette System Temperature, Calibrating Reagent System Temperature, and Calibrating HM Module Temperature procedure in your operator's guide.
- Compare the C4 term on the Calibration Review Data screen to the C4 value on the method insert sheet. If it is not the same, call the Technical Assistance Center. Only logic methods have a C4 term.
- After troubleshooting, repeat calibration. If results are still found to be unacceptable, notify supervisor or director. Suspend testing until problem is resolved.

### 6. RELATED DOCUMENTS

- 1. Dimension Cal Accept Guidelines
- 2. Dimension Calibration summary
- 3. Sample Processing, Siemens Dimension® Xpand, Chemistry procedure
- 4. Startup and Maintenance, Siemens Dimension® Xpand, Chemistry procedure
- 5. Laboratory Quality Control Program, QA policy

### 7. REFERENCES

- 1. Dimension Clinical Chemistry System Electronic Method Procedure Manual
- 2. Dimension RXL Max Clinical Chemistry Operators' Guide August 2008
- 3. Dimension Xpand Chemistry Operator Guide February 2007

Form revised 3/31/0

#### 8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP C044.001		
000	5/24/11	Update owner Section 9: add calibration logs	L Barrett	J Buss
001	9/18/12	Update owner Sections 1 & 2: add analyzer name Section 5: delete drugs of abuse calibration, add step for failure to C & D Section 6: update document titles Section 9: rename Calibration log, remove RXL drugs of abuse log.	L Barrett	R SanLuis
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## ADDENDA AND APPENDICES

Xpand Calibration Log (see Attachment Tab of Infocard)



# **XPAND CALIBRATION LOG**

				_	_		_		
Method Anal									
Room Temperature (Range 22-28C) Acceptable Y/N									
(Verify RM TEMP prior to reconstituting calibrators. It may be necessary to place water and									
calibrators in the hood if RM TEMP is not within the acceptable range, document above)									
Reason for calibration (Check one)									
New Lot Instrument Related QC Problem Calibration Due						ion Due			
❖ Linear Slope Range: 0.97 - 1.03									
		*	Non-Linea	ar Slope	Range:	0.95 - 1	.05		
		*	Enzymes S	Slope Ra	ange:	0.90 - 1	.10		
Calibrator	QC	QC Exp.	Old Lot	Ne	ew Lot	Expecte	d	MEM QC	Accept
Lot/Exp	Lot#	Date	Result	R	Result	Mean +/- 2		SD +/-	Y/N
			1						
			†						
			2:514/1	37.60		-: 01:			
			<u>NEW L</u>	01 (0)	RKELA	<u>IION</u>			
Specimen		Old Lot #		_		New			
	Resu	it 1 H	Result 2	Avera	age Result 1 Result 2			esult 2	Average
1									
3									
3									
	TEA FO	)RMULA:	: [(High R	esult-L	ow Res	sult)/High	Resu	ult]*100	
Specia	men		% Diff		TEA*			Acceptable Y/N	
1									
2							-		
3									
*TEA is availal	ble at - <u>htt</u>	p://questnet1.	qdx.com/Busi	ness_Gro	ups/Medic	al/qc/docs/qc_b	pt_tea	.xls	
*TEA is availal	ole at - <u>htt</u>		qdx.com/Busi				pt tea	.xis	
*TEA is availal	ble at - <u>htt</u>						pt tea	.xls	
*TEA is availal			FOR REV				pt tea	.xls	
	,		FOR REV	/IEWE		ONLY	pt tea	.xls	
Acceptable?	o djustment		FOR REV	/IEWE es		ONLY	pt tea	.xls	

(Attach Calibration Tapes to Reverse)

AG.F112.001 Rev 8/8/12