



TRAINING UPDATE

Lab Location: GEC
Department: Core

Date Distributed: 10/2/2012
Due 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):																									
<p>Startup and Maintenance</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%; padding: 5px;">section</th> <th style="padding: 5px;">description</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; padding: 5px;">1 & 2</td> <td style="padding: 5px;">add analyzer name</td> </tr> <tr> <td style="text-align: center; padding: 5px;">5</td> <td style="padding: 5px;">remove instructions specific to SGAH and/or WAH; change IMT System clean, Stylette HM wash probe & Millipore to monthly frequency, add HM pump heads</td> </tr> <tr> <td style="text-align: center; padding: 5px;">9</td> <td style="padding: 5px;">remove RXL log, add Xpand log</td> </tr> </tbody> </table> <p>Sample Processing</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%; padding: 5px;">section</th> <th style="padding: 5px;">description</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; padding: 5px;">1 & 2</td> <td style="padding: 5px;">add analyzer name</td> </tr> <tr> <td style="text-align: center; padding: 5px;">9</td> <td style="padding: 5px;">rename chart, revise to reflect GEC testing only</td> </tr> </tbody> </table> <p>Calibration / Verification</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%; padding: 5px;">section</th> <th style="padding: 5px;">description</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; padding: 5px;">1 & 2</td> <td style="padding: 5px;">add analyzer name</td> </tr> <tr> <td style="text-align: center; padding: 5px;">5</td> <td style="padding: 5px;">delete drugs of abuse calibration, add step for failure to C & D</td> </tr> <tr> <td style="text-align: center; padding: 5px;">6</td> <td style="padding: 5px;">update document titles</td> </tr> <tr> <td style="text-align: center; padding: 5px;">9</td> <td style="padding: 5px;">rename Calibration log, remove RXL drugs of abuse log.</td> </tr> </tbody> </table>		section	description	1 & 2	add analyzer name	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	9	remove RXL log, add Xpand log	section	description	1 & 2	add analyzer name	9	rename chart, revise to reflect GEC testing only	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.
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Changes on SOPs are blue

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

Non-Technical SOP

Title	Startup 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
<i>Refer to the electronic signature page for approval and approval dates.</i>		
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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1. 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.

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. 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 QC.
 - c. Do not release any patient result until the System check and QC successfully passes.
 - 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 moving.
 - 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.

001015C (PROMOTIONS)

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.
Note: 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 reagent 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 probe.
 - 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.

001015C (PROMOTIONS)

2. 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
 - c. [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.
 - b. 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

8. REVISION HISTORY

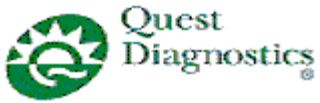
Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP C041.002		
000	2/11/11	Update owner and title page Section 5: item A.8 relocated from end of section, item F added	W. McMillan	Dr Cacciabeve
001	6/8/11	Update owner Section 5: change Stylette HM wash probes and clean windows to 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 _____

MONTH/YEAR _____

DAILY		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)																																	
	Verify Reagent Temp. (2° - 8° C)																																	
	Verify HM Temp. (42° - 44° C)																																	
	Verify System Check																																	
	Cut Waste Film																																	
	Record Millipore Readings																																	
Daily QC Performed and Verified By / Include Initials																																		
WEEKLY		Date and Initials							Date and Initials							Date and Initials							Date and Initials											
	Clean Outside of R2 and HM Wash Probes																																	
	Clean Windows																																	
		Date and Initials							Date and Initials							Date and Initials							Date and Initials											
Replace IMT Sensor Run Dilution Check & Condition Sensor (LOT#)																																		
MONTHLY		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		
	IMT System Clean																																	
	Replace IMT Pump Tubing																																	
	Replace / Clean Air Filters																																	
	Replace HM Pump Heads																																	
	Stylette HM Wash Probes																																	
AS NEEDED	Clean Sample Probe & Drain																																	
	Replace Sample Probe*																																	
	Replace R1 Probe*																																	
	Replace R2 Probe*																																	
	Change Source Lamp																																	
	Replace Chlorine Tablet																																	
	Verify Calibration for the following: CRP (QC ± 1.5sd)																																	

* Replace before or at 30,000 cycles.

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

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
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:	Local Effective Date:	

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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).

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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

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
<i>Refer to the electronic signature page for approval and approval dates.</i>		
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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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

Form revised 03/13/11

Form revised 03/13/11

2. 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 3rd 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
9. 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:
 - 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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- 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

0011CE 0001A00 0001A00

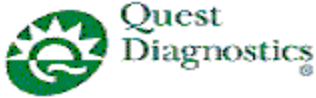
8. REVISION HISTORY

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

9. ADDENDA AND APPENDICES

[Xpand](#) Calibration Log (see Attachment Tab of Infocard)

From revised 2/13/10



XPAND CALIBRATION LOG

Method _____ Analyte _____ Tech _____ Date _____

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

- ❖ *Linear Slope Range:* 0.97 - 1.03
- ❖ *Non-Linear Slope Range:* 0.95 - 1.05
- ❖ *Enzymes Slope Range:* 0.90 - 1.10

Calibrator Lot/Exp	QC Lot#	QC Exp. Date	Old Lot Result	New Lot Result	Expected Mean +/- 2SD	MEM QC SD +/-	Accept Y/N

NEW LOT CORRELATION

Specimen	Old Lot #		Average	New Lot #		Average
	Result 1	Result 2		Result 1	Result 2	
1						
2						
3						

TEA FORMULA: [(High Result-Low Result)/High Result]*100

Specimen	% Diff	TEA*	Acceptable Y/N
1			
2			
3			

*TEA is available at - http://questnet1.gdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls

FOR REVIEWER USE ONLY

Acceptable? Yes No

QC Needs Adjustment in LIS? Yes No

Comment: _____

Reviewed by _____ Date _____

(Attach Calibration Tapes to Reverse)