TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	6/3/2016
Department:	Core	**Due Date:**	6/30/2016
		Implementation:	**7/1/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Calibration / Verification Siemens Dimension® Xpand GEC.C11 v3
Description of change(s):
Section 5E: add lot to lot correlation Appendix A: add steps to program Lot to Lot study on Xpand This revised SOP will be implemented on July 1, 2016

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

Approved draft for training (version 3)

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.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

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1. PURPOSE

This procedure outlines 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

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

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.

- 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.

E. Lot to Lot Correlation:

Unlike calibration which takes place on both Dimension Xpand instruments, the Lot to Lot correlation is routinely performed on Dimension Xpand 1.
For details on Lot to Lot correlations, refer to Reagent Parallel Testing SOP. For instructions to program the Xpand, refer to Appendix A.

- If the result is acceptable, there is no need to do a lot to lot on the other Xpand analyzer.
- Enter results on the "New Reagent Lot or Shipment Comparison Study Form" and attach it to the calibration work up.

Note: If Dimension Xpand 1 is not in use for any reason, lot to lot correlation may be done on the other Xpand analyzer. Specify the instrument used for the correlation on the "New Reagent Lot or Shipment Comparison Study Form."

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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
6. Reagent Parallel Testing, QA procedure
7. New Reagent Lot or Shipment Comparison Study Form (AG.F217)
8. Dimension Xpand Calibration List (AG.F313)
9. Dimension Xpand Calibration Guide (AG.F327)

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

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
002	5/19/16	Section 5E: add lot to lot correlation Section 6: add QA SOP and forms Section 9: remove form, add Appendix A Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett A Chini	R SanLuis

9. ADDENDA AND APPENDICES

~~Xpand Calibration Log~~ (see Attachment Tab of Infocard)

A. Lot to Lot Study on Dimension Xpand Analyzers

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Appendix A

Lot to Lot Study on Dimension Xpand Analyzers

To Program a Lot to Lot study on Dimension Xpand:

1. From the Home Page select **F1 (Enter Data)**.
2. Enter the rack number and sample position
3. Enter a desired sample name
4. Enter a desired sample ID
5. Select the desired test
6. For **Mode** select **Sample Cup**
7. For **Priority** select **XQC**