

TRAINING UPDATE

Lab Location: GEC
Department: Core Lab

Date Distributed: 7/6/2018
Due Date: 7/31/2018
Implementation: 7/11/2018

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Calibration / Verification Siemens Dimension® Xpand GEC.C11 v4
Description of change(s):
<p>Section 5: Updated steps to match practice, included adding new calibrator lot, removed redundant info; renumbered sections</p> <p>Section 6: Removed outdated documents</p> <p>Section 7: Removed RXL guide</p> <p>This revised SOP will be implemented on July 11, 2018</p>

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

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:

Review:		
Print Name	Signature	Date

TABLE OF CONTENTS

1. PURPOSE.....	2
2. SCOPE.....	2
3. RESPONSIBILITY.....	2
4. DEFINITIONS.....	2
5. PROCEDURE.....	2
6. RELATED DOCUMENTS	4
7. REFERENCES	5
8. REVISION HISTORY.....	5
9. ADDENDA AND APPENDICES.....	5

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

No Password required, press ENTER

Press F2: SETUP and RUN

2. Select the **test method** to be calibrated.

3. Select the **calibrator lot number**

- If you do not see the calibrator lot number, you will need to add it (see part B How to Add a Calibrator Lot Number below)

4. After you select the test method to be calibrated, check to make sure you have the correct reagent lot number (upper right side of the screen).
 - a. If this is not the correct lot number, select F1, OTHER LOT.
 - b. If you are calibrating a NEW LOT and you do not see your lot number, then from the OPERATING MENU, go to F4 System Prep → F1 Inventory → F1 Show Hold → F1 Replace 3rd Lot → Press Yes. Repeat Cal/Ver Set Up.
5. Enter all information on screen (tech code, starting cup position, etc.)
6. Verify Calibrator and reagent lot numbers are correct
7. Press F8: QC YES/NO (toggle to select yes)
8. Press F4: Assign cups
9. Press F7: Load/Run
10. Load cups into assigned position
11. Press F4: RUN
12. Once complete, if the values are acceptable, the calibration will “auto-accept” for most assays. If the calibration is not auto-accepted, then from the CALIBRATION MENU:
 - a. Press ENTER
 - b. Press F3, REVIEW DATA
 - c. Select the test method to review.
 - d. Check QC and statistical values. Trouble-shoot if necessary. If values are acceptable, Press F2, ACCEPT. If values are unacceptable, Press F8 REJECT.
13. Perform the lot to lot patient comparisons (see part D below). Complete all paperwork (New Reagent Lot or Shipment Comparison Study form, a.k.a. Lot to Lot form AG.F217 on G-drive), attach printouts, and submit for review.

B. How to add Calibrator Lot Number

1. From Operating Menu:
 - a. Press F5: DEF CAL PRODUCT.
 - b. Scan the bar code on the calibrator package insert with hand held scanner. The screen will populate with calibration values. (Alternatively, you may type in all information manually).
2. Press F7 store
3. Return to Calibration/Verification Set up

C. Troubleshooting Calibration Results

- 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.
- 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. Lot to Lot Correlation:

Although several tests are calibrated 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.”

- Update Calibration information on the Reagent Inventory Sheets (on the G drive).

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. Xpand Calibration Log (AG.F112)~~
9. Dimension Xpand Calibration List (AG.F313)
10. 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
3	5/30/18	Section 5: Updated steps to match practice, included adding new calibrator lot, removed redundant info; renumbered sections Section 6: Removed outdated documents Section 7: Removed RXL guide	D Collier	R SanLuis

9. ADDENDA AND APPENDICES

- A. Lot to Lot Study on Dimension Xpand Analyzers

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**