TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	5/15/2020
Department:	Core Lab	**Due Date:**	6/15/2020
		Implementation:	**5/28/2020**

DESCRIPTION OF REVISION

Name of procedure:
Calibration / Verification Siemens Dimension® Xpand GEC.C11 v5
Description of change(s):
Section 5: Updated menu steps in B.1; added checking reagent correlation factors to C This revised SOP will be implemented May 28, 2020

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**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective 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

   No Password required, press ENTER

   Press F2: SETUP and RUN

2. Select the **test method** to be calibrated.
3. Select the **calibrator lot number** F1

   a. Press Y at the Y/N prompt and ENTER. The Calibration Set Up screen opens.
   b. 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: Process Control
   b. Press F1: Calibration
   c. No password required, press ENTER
   d. Press F5: DEF CAL PRODUCT.
   e. 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, the exit
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.
- Check for updated correlation factors of reagent found on the packing slip in the reagent box (usually on pink paper). Change slope and intercept if necessary.

- 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) and the Dimension Xpand Calibration List.

6. RELATED DOCUMENTS

1. Sample Processing, Siemens Dimension® Xpand, Chemistry procedure
2. Startup and Maintenance, Siemens Dimension® Xpand, Chemistry procedure
3. Laboratory Quality Control Program, QA policy
4. Reagent Parallel Testing, QA procedure
5. New Reagent Lot or Shipment Comparison Study Form (AG.F217)
6. Dimension Xpand Calibration List (AG.F313)
7. Dimension Xpand Calibration Guide (AG.F327)

7. REFERENCES

1. Dimension Clinical Chemistry System Electronic Method Procedure Manual
2. 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

Version	Date	Reason for Revision	Revised By	Approved By
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
4	5/8/20	Section 5: Updated menu steps in B.1; added checking reagent correlation factors to C	R Bridges	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**