TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	5/2/2013
Department:	Chemistry	**Due Date:**	5/31/2013
		Implementation:	**6/1/2013**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Dimension Vista® System Calibration SGAH.C132,WAH.C125 v001
Description of change(s):
Section 5A: Clarified wording Section 5C: Removed Setup and Run, re-numbered subsequent sections Section 5D: Clarified wording, add signature, date and reason for calibration required Section 5E: Clarified wording for troubleshooting Section 5H: Added review and troubleshooting for IMT calibration Section 6: Update Chemistry SOP title This revised SOP will be implemented on June 1, 2013

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

Approved draft for training all sites (version 001)

Non-Technical SOP

Title	**Dimension Vista® System Calibration**
Prepared by	Ashkan Chini Date: 9/27/2012
Owner	Robert SanLuis Date: 9/27/2012

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**

Form revised 3/31/00

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1. PURPOSE

To outline the calibration process for the Siemens Dimension Vista® System.

2. SCOPE

This procedure applies to all Core Laboratory personnel working with the Siemens Dimension Vista System.

3. RESPONSIBILITY

Core Laboratory personnel are responsible for performing and complying with this procedure.
The Core Laboratory Manager/ Supervisor is responsible for content and review of this procedure.

4. DEFINITIONS

None

5. PROCEDURE

A. Calibration Data

A1. View Calibration Information: The calibration information can be viewed for each calibrator lot by two different ways: General or Detail Review.

General Review: From the Home page → **System** → **Method Summary** → Select method → **Calibration**

Detail Review: From the Home page → **Advanced** → **Calibration** → ▼ → select **Calibrations by lot** → Select method

Form revised 3/31/00

A2. Calibrator Needs and Inventory: Automatic calibration requires that calibrators be on the instrument. As the time for processing approaches, the instrument reviews onboard inventory for the appropriate calibrators.

- If a required calibrator is not on board, a red calibrator needs alert appears at the top of the screen.
- To check the calibrator inventory: From the Home page → **Setup** → **Inventory** → **Calibrator Vials**.

A3. Unload Calibrators: Unload calibrators from the system when they expire or are depleted. The carrier with the expired or depleted vial is unloaded to the reagent loading area where it can be removed from the system. Press **Setup** → **Inventory** → **Vial Carriers** → **Unload.**
Note: Re-load unexpired vials that have sufficient volume **WITHOUT** moving their position. If an unexpired vial's position or rack number is changed, the machine will think that vial is a new vial and will give it a full volume and new expiration date.

B. Entering Calibrator IFU Information:

Information from the Calibrator IFU can be entered by scanning the IFU barcode or by typing it onto the screen.

B1. Scanning IFU Information:

1. Press the **Advanced** icon, then the **Calibration** icon. Select **Calibrators** from the menu.
2. Use the handheld barcode scanner to scan the barcode on the IFU. Verify that the screen displays the correct calibrator information.

B2. Manually Entering IFU Information:
If the calibrator information cannot be scanned from the IFU, the data can be entered manually.

1. Press the **Advanced** icon, then the **Calibration** icon. Select **Calibrators** from the menu.
2. From the **Actions** menu on the lower part of the screen, select **New**.
3. Type the appropriate information from the IFU. When finished, press **Save**.

C. Order Calibration

Calibration on the Dimension Vista System takes place automatically from vials onboard the instrument, limiting the need for operator intervention. Make sure to check the current calibrator, QC and reagent's expiration date and volume onboard, if any, before ordering a calibration.

C1. Use this procedure to order a calibration manually:
There are two ways to order calibration:

a. From the Home page:
   1. Verify that calibrators and reagents are in inventory on the instrument.
   2. From the Home page Press **System** → **Method Summary** → **Calibration**.

3. Select a method from the sidebar menu. Select the reagent lot for the method to be calibrated. Press the **Order Calibration** button on the screen.
4. Verify that the information on the screen is correct. Verify that the calibrator lot is correct using the drop-down menu, and then press **OK**.
5. The status field in the calibration screen changes sequentially to Awaiting Scheduling, Preparing Calibrators and Processing.

b. From the Advanced page:
From the Home page press **Advanced → Calibration → Calibrations by lot** → Select the method and lot number → under Order menu bar press **Order Calibration**.

C2. Calibration Using a Cup

Use this procedure for calibrating methods that require calibrator to be supplied in a cup (Hemoglobin A1c and Iron).

1. From the Home page press the **Advanced** icon, then the **Calibration** icon. Select **Calibration by Lot** from the menu.
2. Select a reagent lot for the method to be calibrated.
3. From the Order menu, select **Order Calibration**.
4. Check the **Use Cups** box.
5. Pipette calibrator from the correct lot into a cup.
6. Place the cup in an adapter into position 1 on a rack. For additional cups, use the positions in ascending order. Be sure to use the number of calibration levels and cups as specified in the method IFU.
7. Scan the rack barcode and verify the information on the screen.
8. Press **OK** and load the rack on the instrument.

Note: "Run QC With Calibration" is not implemented for calibration from cups. QC must be manually ordered after calibration is completed.

D. Review Calibration:

The Auto Acceptance mode is active on Dimension Vistas. If the acceptance criteria are met, the calibration is automatically accepted and printed. However, if the acceptance criteria are not met, the status area displays a "Waiting Calibration Review" alert.

1. To review calibration statistics, from the Home page press **System → Method Summary → Calibration**.
2. Press the appropriate method key in the sidebar screen. The acceptance criteria configured for the method is displayed in the table. Review "Overall Acceptance Criteria". If this criteria fails, a message is displayed in the Accept/Reject Calibration Result dialog box.
   a. Study the Slope, Correlation Coefficient, percent deviation. The observed value must be within acceptable range. Look at the graph and the points on it to make sure there is no significant shift.
   b. Evaluate the QC data, make sure there is no significant shift from the QC on the previous lot.

c. To get a detailed summary of the calibration: from the Home page → **Advanced → Calibration → ▼ → Calibrations by Lot** → select the method and appropriate lot number → at the bottom of the page under **Actions** menu select **Show Details**. This page provides every single detail on a calibration including: Run Details, Acceptance Criteria Details, Analyte Reports and Statistics.

3. Press the **Accept/Reject Calibration** button if enabled.
4. Review error messages if displayed and enter comment before accepting or rejecting the calibration.
5. Press **Finish** and retain the printed report for laboratory records.
6. Vista Printer
   a. The Vista printer must be checked regularly during a shift and specifically at the end of each shift to collect the automated accepted calibration papers.
   b. These calibrations must be reviewed and if they meet the acceptance criteria and do not have a significant shift in the QC ranges, no further investigation is needed.
   c. The technologists must sign and date the report, and include the reason for calibration. File the calibration report in the appropriate place as assigned by the Supervisor or Group Lead.

E. Troubleshooting a Failed Calibration

To investigate the source of the problem:

1. From the Home page → **Advanced → Calibration → ▼ → Calibrations by Lot** → select the method and appropriate lot number → at the bottom of the page under **Actions** menu select **Show Details**.
2. If configured criteria fails, then:
   a. Check the volume and expiration date of the current calibrators onboard.
   b. Check the reagent inventory for that specific method and lot number, if the number of tests left on that reagent cartridge is low (anything below 10 is considered low), then replace it with a new fresh reagent cartridge.
   c. Check the volume and expiration date of the QC bottle onboard. Pour fresh QC if needed.
   d. Repeat the calibration now.

3. If a calibration is pending for review due to the QC failure, check the QC bottles onboard and change them if needed and repeat the failed level of QC again.
   a. Once QC is within acceptable ranges go to **System → Method Summary → Calibration → Accept/Reject Calibration** to accept the calibration.
   b. Enter a comment on what has been done and why Calibration is accepted.
   c. Now go to **System → Method Summary → Quality Control.** Select the applicable method and press **ALT** and **P** buttons at the same time so it will print a copy of the screen.
   d. Attach the printed QC page to the calibration page as a proof that the QC was repeated and is acceptable.

4. If failures continue, contact the Siemens Technical Solutions Center.

F. Cancel a Calibration Order:

A calibration order can be cancelled if the status is **Ordered** or **Awaiting Scheduling**. If the status is **Preparing Calibrators**, the calibration has begun and should not be canceled. The calibration can be rejected if the results are not acceptable.
From the Home page → **Advanced** → **Calibration** → ▼ → **Calibrations by Lot** → select the method and appropriate lot number → at the bottom of the page under **Actions** menu select **Cancel order**.

G. Urine Drugs of Abuse Toxicology Calibration

Urine drugs of abuse are calibrated in semi-quantitative mode using multiple levels of the appropriate calibrator.

- Urine drugs of abuse calibrations are run automatically; the instrument will automatically run QC after calibration.
- The instrument will automatically print the calibration report, which includes the numerical QC results. To get the qualitative QC results go to: **System** → **Method Summary** → **Quality Control**. Choose the applicable method and press **ALT** and **P** buttons at the same time so it will print a copy of the screen. Attach the printed QC page to the calibration page.
- If the calibration fails, the instrument will explain what the cause of failure is. Troubleshoot and repeat the calibration and QC if necessary.

H. IMT Calibration

1. The IMT system is calibrated automatically, using a two-point calibration scheme, in the following situations: (During IMT calibration, IMT test processing stops.)
   - at system startup
   - every four hours
   - if the V-LYTE® sensor temperature changes more than 2ºC
   - after successful IMT error recovery
   - after IMT Clean procedure is performed
   - after the V-LYTE® sensor, Standard A or Standard B is replaced
   - after 175 electrolyte samples have been processed

2. To review IMT calibration Details: From the Home page → **System** → **IMT Calibration** → it will show all the details including Slope, Standards A and B, IMT Metrics and IMT pump rate. If all values are within acceptable range and everything is green on the page the calibration is good.

3. To troubleshoot a failed IMT calibration: Always check the IMT consumables and change them if necessary.
   a. Make sure all IMT consumables: Standard B/Salt Bridge, V-LYTE Diluent and V-LYTE Standard A are all pushed all the way down (this is the primary reason most IMT Calibrations fail).
   b. Then From the Home page → **System** → **IMT Calibration** → **Maintain IMT** → **Prime IMT** → Prime Salt Bridge and Solutions A and B. To prime the V-LYTE Diluent IMT probe will need to be paused. After priming all solutions a few times, recalibrate the IMT.

c. If failures continue, contact the Siemens Technical Solutions Center.

K. Calibration Schedule Form:

The Dimension Vista Calibration List (see addenda) is a communication tool. It is placed on each instrument by Group Leads to inform technologists of –

- assays that require recalibration for Quality Control purposes
- assays have recently been received and require calibration followed by Lot to Lot correlation

L. Lot to Lot Correlation:

Unlike calibration which takes place on every Dimension Vista, the Lot to Lot correlation will only take place on Dimension Vista 1 at both sites (Shady Grove and Washington Adventist). For step by step instructions and details on Lot to Lot correlations refer to Reagent Parallel Testing SOP

- If the result is acceptable, there would be no need to do a lot to lot on the rest of Dimension Vista analyzers.
- Use the "New Reagent Lot or Shipment Comparison Study Form" and attach it to the calibration work up.

6. RELATED DOCUMENTS

Dimension Vista® Sample Processing, Startup and Maintenance, Chemistry procedure
Quality Control Program, QA policy

7. REFERENCES

Dimension Vista System, Operator's Guide. Siemens Healthcare Diagnostics, Inc. Revised 03/2011.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
000	4/9/2013	Section 5A: Clarified wording Section 5C: Removed Setup and Run, re-numbered subsequent sections Section 5D: Clarified wording, add signature, date and reason for calibration required Section 5E: Clarified wording for troubleshooting Section 5H: Added review and troubleshooting for IMT calibration Section 6: Update Chemistry SOP title	A Chini L Barrett	R SanLuis

9. ADDENDA AND APPENDICES

Dimension Vista Calibrator Guide (see Attachment Tab of Infocard)
Dimension Vista Calibration List (see Attachment Tab of Infocard)
New Reagent Lot or Shipment Comparison Study Form (see Attachment Tab of Infocard)