Quest Diagnostics

TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	11/6/2012
Department:	Core	**Due Date:**	12/1/2012

DESCRIPTION OF PROCEDURE

Name of procedure:

Dimension Vista® Sample Processing, Startup and Maintenance WAH.C126,SGAH.C133 v000

Attachments:

Dimension Vista Limits Chart

Millipore Water Sampling for Culture on Dimension Vista Systems

Dimension Vista® System Calibration WAH.C125, SGAH.C132 v000

Attachments:

Dimension Vista Calibrator Guide

Dimension Vista Calibration List

New Reagent Lot or Shipment Comparison Study Form

Description of change(s):

New SOPs for new Chemistry analyzers

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

Approved draft for training all sites (version 000)

Non-Technical SOP

Title	**Dimension Vista® Sample Processing, Startup and Maintenance**
Prepared by	Ashkan Chini Date: 7/12/2012
Owner	Robert SanLuis Date: 7/12/2012

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:	

12 month (or new) management review and approval: Signature acknowledges SOP version remains in effect with NO revisions.		
Print Name	**Signature**	**Date**

Form revised 3/31/00

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1. PURPOSE

To outline the operational daily start up procedure for the Siemens Dimension Vista 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 Vista 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

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).

B. Operating Dimension Vista

B1. Sample Container and Racks
B2. Sample Preparation
B3. Sample Orders
B4. Process Samples
B5. Test Results

B1. Sample Container and Racks

1. Adapters and acceptable Tubes

All sample containers except the 10 mL tube require an adapter. The adapter for 5 mL tubes is teal and the adapter for 7 mL tubes is beige. These adapters must be used because they have specific codes that identify them to the instrument.

Sample Container	Acceptable Rack	Adaptor Type	Adaptor Color	Adaptor Code	Volume	Size
Red top Tube / Lavender top Tube	Grey / Orange	5 mL	Teal		4 mL	13 x 75 mm
Green top Tube / Red top Tube	Grey / Orange	7 mL	Beige		4.5 mL	13 x 100 mm
SST	Grey / Orange	None	None	None	7.5 mL	16 x 100 mm
Open Glass Tubes (Urines)	Yellow	None	None	None	7.5 mL	16 x 100 mm

2. Dimension Vista® Sample Cups

a. The maximum fill volume for sample cups is 1.0 mL of fluid.
b. The operator must ensure there is sufficient sample in the cup. When using a sample cup, be sure the lid is closed securely so it does not interfere with probe movement.
c. When loading a cup into the required adapter, be sure to seat it securely, with the bottom of the cup lid touching the top of the adapter.
d. The dead volume in a sample cup on a 5 or 7 mL adapter is 20 µL.
e. The dead volume in a sample cup on a limited rack is 10 µL.
f. The dead volume must be added to the required sample volume displayed on the Manual Order Entry screen.

3. Dimension Vista® Small Sample Containers

a. Dimension Vista® Small Sample Containers are intended to be used when the aliquot probe cannot reach the sample in a primary barcoded tube. In these situations, using Dimension Vista® Small Sample Containers allow efficient sample processing by retaining the use of the barcode information on the primary tube.
b. Fill the Dimension Vista® Small Sample Container with a maximum of 1.0 mL of sample, the dead volume is 100 µL.

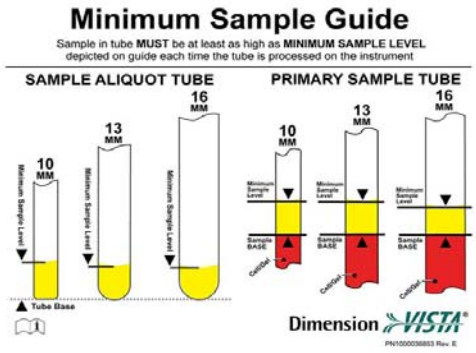
4. **Sample Racks**
   a. Sample racks hold six samples and are barcoded for identification to the system.
   b. Each position on a rack is numbered so that the system can communicate the exact location of a sample.

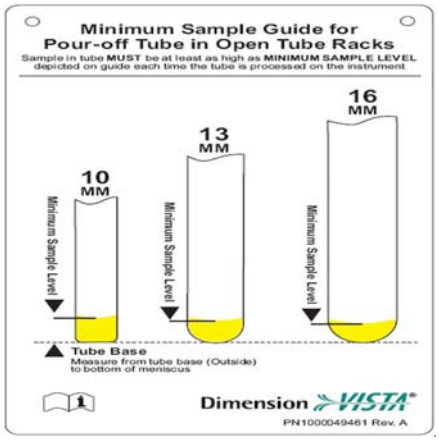
   - **Surplus Rack (Grey Color):** The sample volume aspirated from a Surplus rack is greater than the amount needed to process the scheduled tests. This option allows for unplanned testing such as add-on tests, dilutions and reflex testing. The minimum sample volume is 200 µL. The total minimum sample in the container is 200 µL plus the dead volume of the container being used.

   - **Limited Rack (Orange Color):** The sample volume aspirated from Limited racks is only the amount needed to run scheduled tests. No add-on tests or re-runs are allowed on samples aliquotted from limited racks. The instrument attempts to retry on process errors; however there must be sufficient volume remaining in the aliquot. HIL tests are not automatically ordered but are processed if requested by the operator (manually ordered). Dead volume for a sample cup in a limited rack is 10 µL. The minimum sample volume is 50 µL. The total minimum volume that must be in a limited SSC is 60 µL.

   - **Urine Rack (Yellow Color):** Open glass tubes only.

5. **Adequate Sample Volume:**
   a. Before loading a sample tube into a rack, use one of the two Minimum Sample guides as a quick check for adequate sample volume in the primary sample tube or sample aliquot tube.
   b. Hold the appropriate type of sample tube up to the guide for that size tube.
   c. If the sample is within the indicated sufficient sample height area, there is adequate sample volume to run that sample.





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B2. Sample Preparation

Barcode Label Placement: Refer to this picture for proper barcode label placement. Labels should be within the area defined by the horizontal lines.

B3. Sample Orders

Manual Order Entry: If a specimen needs to be ordered or repeated manually for any reason, use the following instruction:

1. Press **Patient Samples > Manual Order Entry**.
2. Fill in the fields on the screen.
3. Required fields are **sample ID** and **sample fluid type**. The method sidebar displays the appropriate fluid panels and methods for the sample fluid type entered.
4. Select up to 60 tests or panels from the Methods/Panels sidebar menu.
5. When ordering a manually prepared diluted sample, enter the dilution factor in the Manual Dilution factor field. The instrument automatically multiplies the result by the factor. When a factor is entered, other than 1.0, the sample is not auto-diluted by the instrument.
6. To print a barcode label for a sample cup, press **Print Barcode** after the data fields on the screen have been filled in. On the dialog box that appears, press "Print Sample Cup Barcode".
7. Select an option sample to be run from the drop down menu.
8. Press **Submit Order**.

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B4. Process Samples

1. Load Racks onto the Instrument

a. Place the rack in the input lanes (the left instrument on a Dimension Vista® 1000T System). It is moved automatically to the (designated) aliquot area.
b. When aliquotting is complete, the rack is shuttled to the output lanes (the right instrument on a Dimension Vista® 1000T System) where it can be removed.

2. STAT Sample Processing

a. Use the STAT lane for STAT samples, **whole blood methods**, and priority tests.
b. Place barcoded sample containers in a rack.
c. Place the rack in the STAT lane located to the right of the output lane.
d. After the samples are aliquotted, the rack moves out through the sample output lane.

3. Whole Blood Sampling

a. Surplus samples presented in a tube or sample cup must be placed in the STAT lane. Sample cup minimum fill is 200 µL.
b. Samples presented in tubes or cups via the routine lanes are not supported and yield both the problem sample "Failed to Create One or More Aliquots" and the process error "Routine Tube Whole Blood Processing Not Supported".
c. Surplus samples presented in any SSC (small sample containers) can be placed in the routine lanes and STAT lane without any errors. There is no limit to the number of SSC that can be used at a single time because whole blood samples placed in SSC are automatically re-suspended prior to aspiration, to allow for routine lane entry. Minimum fill is 400 µL. The maximum fill is 1 mL.
d. Limited samples for whole blood sampling is not supported.

4. View Samples

Use one of these methods to view the progress and status of a sample:

Sidebar Samples Option

The Samples option in the sidebar display shows samples in real time as they are processed on the system. The display is constantly refreshed as testing takes place and the sample status changes. On the Dimension Vista® 1000T System, the twin icon displays which instrument the sample was processed on.

Press the **Samples** button on the Sidebar menu.

There are three options for viewing samples in the sidebar:

- **Processing.** Displays status and estimated time to completion.
- **Completed.** Displays completed samples.
- **STAT Only.** Displays only STAT samples.

Patient Samples Menu

Use these Patient Sample menu options to view samples:

- All Samples > Sample List
- All Samples > Search Samples

- STAT Samples
- Add On Tests
- Sample History

5. **Search Samples**
   a. The search samples screen finds a specific sample on the list, based on search criteria entered.
   b. The operator can search for a character or number string. Type the data in the Search field and press the **Go** button. All samples meeting the criteria are listed on the screen. Select the patient to view the results.
   c. The handheld barcode scanner can also be used to scan the barcode label on the tube.

6. **Add-On Tests**
   a. Go to **Patient Samples > All Samples**. Select sample.
   b. Press **Add-on Tests** button to order additional tests for a sample that has already been placed on the instrument.
   c. Order tests using the Methods sidebar or the Query LIS button.
   d. Specify if sample is to be obtained from an existing aliquot plate or from the rack with the reloaded sample.

7. **Cancel Tests**
   A test can be cancelled on a patient sample that is processing. **Manually Cancelled Test** appears on the test result report in the flag field.
   a. Select **Patient Samples > All Samples > Sample List**.
   b. Select the patient sample from the sample list on the Results screen.
   c. Highlight the test to be cancelled.
   d. Press **Cancel Selected Tests**. Dialog box appears to confirm selected test.

B5. Test Results

1. **Display Test Results**
   Use the **Patient Samples > All Samples > Results** screen to view test results for a patient.

2. **Print Test Results**
   If a printout of the results is needed, press the **Print** button at the bottom of the screen.

3. **Retransmit to LIS**
   To retransmit results to the LIS, press the **Retransmit** button. Results for the displayed sample are transmitted.
   If not all tests are finished processing, the completed results are sent as a partial report.

4. **HIL Index**
   The HIL reporting feature, which alerts the operator to potential interference from hemolysis, icterus and lipemia in a sample, provides a numerical index for each interference attribute.
   - H = hemoglobin resulting from lysis of red blood cells
   - I = icterus resulting from endogenous bilirubin
   - L = lipemia or turbidity caused by insoluble lipids

5. **Automatic Dilution (Autodilution)**
   When the system dilutes a sample automatically, the message **Diluted** appears on the test results report.
   If the diluted sample still produces a result outside the assay range for the method, the flags **Below Assay Range** or **Above Assay Range**, and the comment **Diluted** appears on the test report with the method. If this occurs, dilute the sample manually and use the Manual Order Entry screen to rerun the test, enter the dilution factor to determine the correct test result.

C. Daily Startup

1. **Perform these tasks every 24 hours**
   Navigate to **System > Daily Log > Daily Setup Log**.
   Perform the following tasks:

   a. Probe Test (The probe test is scheduled automatically as part of off-peak activities)

   Interpreting Probe Test Result:

Result	Explanation
SKIP	The test was not done because a prerequisite test failed. For example, if alignment verification for a probe fails, its tubing integrity test is not run.
GRAY	If the area is grayed out, the test is not applicable for the probe.
ERROR	A mechanical error occurred during the test. Creates a red alert.
FAIL	The test was completed but the result was outside the acceptable range. Creates a red alert.
PASS	No errors occurred during the test and the result was within the acceptable range.

   b. Review temperatures and humidity
   c. Clean the sample lane area and inspect the sample racks Wipe the areas around the sample rack handling area and STAT lanes with a damp cloth. Inspect the sample racks and clean with soapy water as needed.
   d. Empty waste as indicated by alerts
   e. Replenish supplies as indicated by alerts:
      - Load Aliquot Plates
      - Load Cuvettes
      - Empty Waste
      - Load LOCI® Reaction Vessels
      - IMT consumables

- System Fluids
- Reagent Needs

f. View Hydration Status

g. When the tasks are completed record the tasks on the Daily Setup Log by selecting the "Yellow X" in the complete column. A green "Check Mark" appears along with the date. These tasks are documented electronically.

2. Off-Peak Activities

Off-peak activities are scheduled to start within a 4 hour user-defined window. The system automatically starts off-peak activities during this time frame.

The system performs the following activities:

a. Runs Probe Test
b. Routine IMT Clean
c. Discard expired aliquot plates
d. Backup Database
e. Hydrates Reagents (that are needed in the next 24 hours)
f. Orders Calibrations that are near expiration (that are configured for auto-trigger and expiration)
g. Zip Milipore Data Files
h. If probe test is configured, the instrument pauses and enter Diagnostics mode. The remaining activities do not interfere with normal processing.

D. Maintenance

1. General information and schedule

a. The Daily Log and weekly / monthly maintenance will be performed as specified below

Site	Instrument	Shift
SGAH	Vista 1	Day
SGAH	Vista 2	Night
SGAH	Vista 3	Evening
WAH	Vista 1	Night
WAH	Vista 2	Day

b. The daily monitoring of the instrument supplies and waste will be performed on all three shifts.
c. The Core Laboratory Group Leads are responsible for the weekly review of maintenance logs. This is documented on the QC Summary Report.
d. The Core Laboratory Supervisor, Operational Director or designee is responsible for the monthly review of maintenance.
e. The required maintenance must be completed as scheduled.
f. After any maintenance is completed, Quality Control must be run successfully before releasing patient results.

2. Basic Steps and Tools needed for Maintenance

Always pause the instrument first. To open the Lids:

a. Insert a long slender tool in the hole next to the STAT lane. Press firmly against the latch and lift the lid.
b. Insert the tool into the hole at the center of the center lid. Press firmly against the latch and lift the lid.
c. Close the lids and press the **Operation** icon to display the drop-down menu. Press **Reset** to return system status to **Ready**.

3. Accessory Spare Parts Kit

Parts and tools needed for maintenance and replacement procedures can be found in the accessory spare parts kit that comes with the instrument.

4. Weekly Maintenance:

Weekly Maintenance Log

Navigate to **System > Daily Log > Weekly Maintenance Log**.
Perform the following:

Clean Reagent Residue on Baseplate:

a. Press the **Operation** icon, then the **Pause** button to pause the instrument.
b. Release the center cover interlock and raise the center lid of the instrument and locate the baseplate.
c. Clean the areas around Reagent Arms 1 and 2 as needed using a damp cloth.
d. Close the instrument lids and press the **Operation** icon, then **Reset**.

Inspect IMT Module Sample Port for Salt Crystals

a. Press the **Operation** icon, then the **Pause** button to pause the instrument.
b. Release the center cover interlock and raise the left and center instrument lids and locate the IMT module area.
c. Gently pull on the rectangular latch on each side of the aliquot plate holder to release the aliquot plate cover. Set the cover aside.
d. Locate the IMT Sample Port. If salt crystals are present, clean as needed using a damp cloth.
e. Close the instrument lids and press the **Operation** icon, then **Reset**.

f. When completed, record the tasks on the Weekly Maintenance Log. Click on the "Yellow X" in the complete column and a green "Check mark" appears along with the date. These tasks are documented electronically.

Note: These procedures are instrument specific and need to be performed on each side of a Dimension Vista® 1000T System.

5. Monthly Maintenance

Monthly Maintenance Log

a. Perform these tasks monthly, using the following supplies:
- Flex® Inserts
- Air Filters
- Drain Brush
- Gauze
- Long Slender Tool
- Alcohol Prep Pad

b. Navigate to **System > Daily Log > Monthly Maintenance Log**.

c. Perform the procedures in the following order:
1) Inspect IMT Peristaltic Pump Tubing for flattened areas.
2) Clean Reagent Flex® Inserts:
   Dimension Vista® 1000T: only clean Reagent Arm 1 and 2 Flex® Inserts.
   Dimension Vista® 1500: clean the Reagent Arm 1, 2, and 3 Flex® Inserts.
3) Clean the aliquot, IMT, sample, reagent and reagent prep drains.
4) Clean Aliquot Probe Tip using alcohol prep
5) Replace Air filters
6) Clean Aliquot Waste Chute

d. When completed, record the tasks on the Monthly Maintenance Log. Click on the "Yellow X" in the complete column and a green "Check Mark" appears along with the date.

6. As Needed Maintenance:

a. Replace Water Purification Module (WPM) Components

Note: This procedure is instrument specific and needs to be performed on each side of a Dimension Vista® 1000T System.

The WPM alerts the user when a component needs to be replaced or cleaned. The user can manually perform maintenance on the following components:
1) Q-Gard Replacement
2) Progard Replacement
3) Sanitization
4) pH Cleaning (A)
5) pH Cleaning (B)

To replace a component of the WPM:
1) Press the alert or press **Setup >Supplies > Maintain Water Supply**.
2) The WPM Main page opens.
3) Select the **Alarms-Events** button to view the component requiring attention.
4) Select the **Maintenance** button from the WPM menu.
5) Select the maintenance to be performed.

b. Replace Progard® Pretreatment Pack

1) Open the left-hand door. The WPM sits on a movable tray.
2) Pull up on the metal ring/black knob in the right front corner to release the tray. Pull the tray forward.
3) Locate the Progard® Pretreatment Pack.
4) Press the **Maintenance** button on the WPM screen. Press **Progard Replacement** button, then press **Continue**.
5) Follow the instructions (listed below) on the screen to replace the pack:
   a) Lift the pack adapter cover to the top position. Remove the metal locking clip and pull out the Progard.
   b) Remove the protective caps from the new Progard and wet the pack o-rings using a few drops of water.
   c) Slide the pack onto the metal guide pin. Lift up the Progard slightly in order to push the bottom of the pack into the slot at the bottom of the system.
   d) Push the Progard completely onto the pack adapter. The metal guide pin should be visible now. Lock the Progard in place with the metal locking clip on the end of the metal guide pin. Lower the adapter cover over the newly installed Progard.
6) When completed press **Finish**. The Maintenance Complete screen is displayed. Press **Finish** again.
7) Record this replacement in the Instrument Log.

c. Replace Q-Gard® Polishing Pack

1) Open the left-hand door. The WPM sits on a movable tray.
2) Pull up on the metal ring/black knob in the right front corner to release the tray. Pull the tray forward.
3) Press the Alert or **Setup > Supplies** to display the Supplies screen. Press **Maintain Water Supply**.
4) Press the **Maintenance** button on the WPM screen. Press **QGard Replacement** button, and press **Continue**. The system depressurizes.
5) Follow the instructions (listed below) on the screen to replace the pack:
   a) Lift the pack adapter cover to the top position. Remove the metal locking clip. Pull out the Q-Gard.
   b) Remove the protective caps from the new Q-Gard and wet the pack o-rings using a few drops of water.
   c) Slide the pack onto the metal guide pin. Lift up the pack slightly in order to push the bottom of the pack into the slot at the bottom of the system.
   d) Push the pack completely onto the pack adapter. The metal guide pin should be visible now. Lock the pack in place with the metal locking clip on the end of the metal guide pin. Lower the adapter cover over the newly installed Q-Gard.
6) When finished, press **Next**. The Maintenance Complete screen is displayed. Press **Finish**.
7) Record this replacement in the Instrument Log.

d. Sanitize the RO Membrane

Use this procedure to sanitize the RO Membrane when prompted by an Alert (approximately every 60 days).

1) Open the left-hand door. The WPM sits on a movable tray.
2) Pull up on the metal ring/black knob in the right front corner to release the tray. While pulling on the ring, pull the tray forward.
3) Press the Alert or **Setup > Supplies** to display the Supplies screen. Press **Maintain Water Supply** to display the dialog box.
4) Press **Maintenance** and follow the instructions to begin the sanitization cycle. Follow the instructions; the system will ask for a chlorine tablet soon.
5) Record the procedure in the Instrument Log.

e. pH Clean

Use this procedure to perform a pH clean of the RO Membrane when prompted by an Alert.

1) Open the left-hand door. The WPM sits on a movable tray.
2) Pull up on the metal ring/black knob in the right front corner to release the tray. While pulling on the ring, pull the tray forward.
3) Press the Alert or **Setup > Supplies** to display the Supplies screen. Press **Maintain Water Supply** to display the dialog box.
4) Press **Maintenance** and follow the instructions to begin the pH clean cycle.
5) Record the procedure in the Instrument Log.

f. Water Sampling for Culture (to be done once a month on every Dimension Vista)

1) Log on as an Administrator.
2) Press **Operation > Pause**.
3) Press **Advanced > Diagnostics**.
4) Select **System Diagnostics** from the Diagnostics menu.
5) Select **Vista Diagnostics** from the Diagnostic Tasks menu.
6) Select the **Prime** tab.
7) To set up the flush for Reagent Arm 2 (R2 arm), enter 11 into the Reagent Arm 2 field. Select Prime Pumps for Reagent Arm 2.
8) Release the interlock and raise the center lid.
9) Get the sterile cup or sampler assembly ready.
10) Write the date, type, and sampling site on the outside of the collection case.
11) Remove the cover from the R2 arm by pressing in and up on the latch and lifting the cover off the arm assembly.
12) Remove the fitting from Reagent Probe 2.
13) Place the collection case under the R2 Arm tubing and fitting.
14) While holding the collection case under the tubing and fitting, select the Reagent Arm 2 **Prime Pumps** button and collect the appropriate volume to fill the collection case.
15) Reconnect the R2 probe tubing to its fitting and reinstall the R2 arm cover if removed in Step 12.
16) Prime the Reagent Arm 2 pump 5 times by selecting **5** next to the Reagent Arm 2 field.
17) After the probe has completed priming, select the **Instrument** tab. Select the **Exit Diagnostics** button. Select **Yes** to exit.

18) Close the instrument lid.
19) Select the **Home** icon at the top of the screen.
20) Navigated to **System > Daily Log**, then select **Run Probe Test** button. This ensures that the probe has been fitted correctly after sampling. If the probe test fails, adjust the probe to its fitting until it is secure, then prime the Reagent Arm 2 pump again an perform the probe test until it passes for Reagent Arm 2.
21) Document collection on Millipore Water Sampling for Culture log.
22) To order culture:
    a) Complete a microbiology downtime form with
        - name of the Lab section ordering
        - date and time water is collected
        - name of test ordered
    b) Use one of the labels attached to the form to label the specimen
    c) Deliver specimen to Specimen Processing
    d) Specimen Processing staff will:
        - Order XH20 in LIS
        - Label the specimen and downtime form with the LIS order
        - Deliver sample to Microbiology
    e) Microbiology staff will:
        - Inoculate a Standard Methods Agar (SMA) plate with 1 mL of water utilizing a 1 mL pipette.
        - Let plate sit in hood specimen side up until water absorbs into medium.
        - Send to Chantilly for incubation and reading.
23) Culture result will be processed as follows. Group Lead will:
    a) Retrieve results from printer
    b) Record results as CFU/mL on the Millipore Water Sampling for Culture Log
    c) Acceptable values are ≤ 10 CFU/mL.
    d) Document corrective action if value is unacceptable.

g. **Probe Replacement**

Note: This procedure is instrument specific and needs to be performed on each side of a Dimension Vista® 1000T System.

1) **Replace a Reagent Probe** (When the Reagent Probes count reaches 1,170,000 cycles, a yellow system alert is generated. When the count reaches 1,200,000 cycles a red system alert is generated).
2) **Replace the Reagent Preparation Probe** (When the Reagent Preparation Probe count reaches 28 hours a yellow system alert is generated. When the count reaches 30 hours a red system alert is generated).
3) **Replace other probes as needed.**

6. RELATED DOCUMENTS

Quality Control Program, QA procedure
QC Responsibilities and Review, QA procedure

7. REFERENCES

Dimension Vista® System Operator's Guide, Siemens Diagnostics, revised 03/2011.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA AND APPENDICES

Dimension Vista Limits Chart (see Attachment tab of Infocard)
Millipore Water Sampling for Culture on Dimension Vista Systems (see Attachment tab of Infocard)

Form revised 3/31/00

DIMENSION VISTA® LIMITS CHART

☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT	SGAH	WAH
ACTM	µg/mL	2	2.0 - 600.0	3	2.0 - 900.0	Drug 2 Cal Level 1, or Drug Free Serum	x	x
ALB	g/dL	4	0.0 - 32.0	Not Available	0.0 - 32.0	Do NOT Dilute	x	x
ALC	mg/dL	4	3 - 1,200	Not Available	3 - 1,200	Do NOT Dilute	x	x
ALP	U/L	2.33	4 - 2,330	10	4 - 10,000	Enzyme Diluent	x	x
ALTI	U/L	3.5	6 - 3,500	10	6 - 10,000	Enzyme Diluent	x	x
AMON	µmol/L	2	25 - 2,000	3	25 - 3,000	Water	x	x
AMY	U/L	2	2 - 1,300	10	2 - 6,500	Enzyme Diluent	x	x
AST	U/L	2	3 - 2,000	10	3 - 10,000	Enzyme Diluent	x	x
BUN	mg/dL	4	1 - 600	Not Available	1 - 600	Do NOT Dilute	x	x
CA	mg/dL	2	5.0 - 30.0	3	5.0 - 45.0	Water	x	x
CHOL	mg/dL	4	50 - 2,400	5	50 - 3,000	Water	x	x
CKI	U/L	7	7 - 7000	40	7 - 40,000	Water	x	x
CL	mmol/L	Not Available	50 - 200	Not Available	50 - 200	Do NOT Dilute	x	x
CRBM	µg/mL	4	0.5 - 80.0	Not Available	0.5 - 80.0	Do NOT Dilute	x	x
CREA	mg/dL	2	0.1 - 40.0	3	0.1 - 60.0	Water	x	x
CRP	mg/dL	20	0.3 - 380.0	Not Available	0.3 - 380.0	Do NOT Dilute	x	x
CTNI	ng/mL	Not Available	0.02 - 40.00	5	0.02 - 200.00	CTNI Sample Diluent	x	x
DBIL	mg/dL	4	0.1 - 64.0	5	0.1 - 80.0	Water	x	x
DGNA	ng/mL	Not Available	0.06 - 5.00	10	0.06 - 50.00	Drug 4 Cal. Level 1 or Digoxin-Free Serum	x	x
ECO2	mmol/L	Not Available	1 - 45	2	1 - 90	Water	x	x
FT4	ng/dL	Not Available	0.10 - 8.00	Not Available	0.10 - 8.00	Do NOT Dilute	x	x
GENT	µg/mL	4	0.2 - 48.0	Not Available	0.2 - 48.0	Do NOT Dilute	x	x
GGT	U/L	2	3 - 1,600	20	3 - 16,000	Enzyme Diluent	x	x
GLUC	mg/dL	4	1 - 2,000	5	1 - 2,500	Water	x	x
HCG	mIU/mL	200	1 - 200,000	5	1 - 1,000,000	Water	x	x
HDLC	mg/dL	4	3 - 600	Not Available	3 - 600	Do NOT Dilute	x	x
IRON	µg/dL	2	5 - 2,000	3	5 - 3,000	Water	x	
IBCT	µg/dL	2	8 - 2,000	3	8 - 3,000	Water	x	
K	mmol/L	Not Available	1.0 - 10.0	Not Available	1.0 - 10.0	Do NOT Dilute	x	x
LA	mmol/L	4	0.1 - 60.0	Not Available	0.1 - 60.0	Do NOT Dilute	x	x
LDI	U/L	4	6 - 4,000	20	6 - 20,000	Enzyme Diluent	x	x
LI	mmol/L	Not Available	0.20 - 5.00	3	0.20 - 15.00	Lithium Free Serum	x	x
LIPL	U/L	2	10 - 3000	10	10 - 15,000	Water	x	x
MG	mg/dL	2	0.2 - 40.0	3	0.2 - 60.0	Water	x	x

Quest Diagnostics

DIMENSION VISTA® LIMITS CHART

☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT	SGAH	WAH
MMB	ng/mL	20	0.5 - 6,000.0	Not Available	0.5 - 6,000.0	Do NOT Dilute	x	x
MYO	ng/mL	20	1 - 20,000	Not Available	1 - 20,000	Do NOT Dilute	x	x
NA	mmol/L	Not Available	50 - 200	Not Available	50 - 200	Do NOT Dilute	x	x
PHNO	µg/mL	4	2.1 - 320.0	Not Available	2.1 - 320.0	Do NOT Dilute	x	x
PHOS	mg/dL	2	0.1 - 18.0	5	0.1 - 45.0	Water	x	x
PTN	µg/mL	4	0.4 - 160.0	Not Available	0.4 - 160.0	Do NOT Dilute	x	x
SAL	mg/dL	3	1.7 - 300.0	Not Available	1.7 - 300.0	Do NOT Dilute	x	x
TBIL	mg/dL	4	0.1 - 100.0	5	0.1 - 125.0	Water	x	x
TGL	mg/dL	4	2 - 4,000	5	2- 5,000	Water	x	x
THEO	µg/mL	4	2.0 - 160.0	Not Available	2.0 - 160.0	Do NOT Dilute	x	x
TOBR	µg/mL	4	0.3 - 48.0	Not Available	0.3 – 48.0	Do NOT Dilute	x	x
TP	g/dL	2	0.0 - 24.0	3	0.0 - 36.0	Water	x	x
TSH	µIU/mL	5	0.01 - 500.00	Not Available	0.01 - 500.00	Do NOT Dilute	x	x
UCFP (CSF)	mg/dL	1.84	5 - 460	10	5 - 2500	Water	x	x
URCA	mg/dL	4	0.2 - 60.0	5	0.2 - 75.0	Water	x	x
VALP	µg/mL	2	3.0 - 300.0	3	3.0- 450.0	Drug 2 Cal Level 1, Drug Free serum, or Water	x	x
VANC	µg/mL	Not Available	0.8 - 50.0	3	0.8 - 150.0	Drug Cal 2 Level 1, Drug Free Serum, or Water	x	x

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT	SGAH	WAH
Urine CREA	mg/dL	Not Available	0.1 - 200.0	3	0.1 - 600.0	Enzyme Diluent	x	x
Urine K	mmol/L	Not Available	1.0 - 300.0	Do Not Dilute	1.0 - 300.0	Do Not Dilute	x	x
Urine SOD	mmol/L	Not Available	5 - 300	Do Not Dilute	5 - 300	Do Not Dilute	x	x
UCFP (urine only)	mg/dL	1.84	5 - 460	10	5 - 2500	Water	x	x
HA1C	%	Not Available	3.5 - 16.0	2	3.5 - 32.0	Water	x	x

☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

Millipore Water Sampling for Culture on Dimension Vista Systems

Dimension Vista #: _____ **Serial #:** _____

Performed monthly

Collect Water for Bacterial Content	**Tech:**	**Tech:**	**Tech:**
	Date:	**Date:**	**Date:**
Bacterial Content Result **Acceptable value:** ≤ 10 CFU/mL Document corrective action if unacceptable			

Monthly review:	Monthly review:	Monthly review:

Approved draft for training all sites (version 000)

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:	

12 month (or new) management review and approval: Signature acknowledges SOP version remains in effect with NO revisions.		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

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 using the **Method Summary > Calibration** screen. Additional information can be obtained using the Advanced Function, **Calibration > Calibration by Lot > Show Details**. (This information is shared data, viewable on each side of a Dimension Vista® 1000T System.)

A2. Calibrator Needs: 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. The **Needs > Calibrator Vials** screen shows the calibrator lots that need to be loaded. Press the alert or **Setup > Needs > Calibrator Vials** to display the screen. (This information is instrument specific and needs to be viewed individually on the left and right sides of a Dimension Vista® 1000T System).

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.** Re-load unexpired vials that have sufficient volume.

A4. Calibrator Inventory: Calibrator vials currently onboard are listed on the **Inventory > Calibrator Vials** screen. Each calibrator vial is listed with its Carrier ID, Name, Level, Lot Number, Available Volume and Expiration date. From this screen the list of onboard calibrator vials can be printed by pressing the **Print** button. (This information is shared between the left and right instruments on a Dimension Vista® 1000T System).

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. (This information is shared on both sides of a Dimension Vista® 1000T System)

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. Set Up and Run Calibration:

C1. Load Reagent Cartridges on the Dimension Vista for Calibration

C2. Offboard Calibrator Preparation:

Calibrators are either ready-to-use in a barcoded vial, or require preparation before use. The calibrator barcode label contains the following information:

- calibrator catalog and lot numbers
- fill volume
- expiration date

C3. Load Calibrators. (Calibrator IFU's are shared and can be scanned on the left or right side of a Dimension Vista® 1000T System.)

D. Order Calibration

Calibration on the Dimension Vista® System takes place automatically from vials onboard the instrument, limiting the need for operator intervention.

D1. Use this procedure to order a calibration manually:

1. Verify that calibrators and reagents are in inventory on the instrument.
2. Press **System > Method Summary > Calibration**.
3. Select a method from the sidebar menu. 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.

D2. Calibration Using a Cup

Use this procedure for calibrating methods that require calibrator to be supplied in a cup (Hemoglobin A1c and Iron). For Dimension Vista® 1500 System operators, skip Step 9. For Dimension Vista® 1000T System operators, skip Step 8.

1. 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.
9. Press **OK** and load the rack on the left instrument.

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

E. Review Calibration:

When calibration is complete:

- If Auto Acceptance is enabled and the acceptance criteria are met, the calibration is automatically accepted and printed.
- If Auto Acceptance is enabled, but the acceptance criteria is not met, the status area displays a "Waiting Calibration Review" alert.

1. To review calibration statistics, 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.
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. (This information is shared between the left and right instruments of a Dimension Vista® 1000T System.)

F. Troubleshooting a Failed Calibration

1. Press the **Advanced** icon, then the **Calibration** icon. Select **Calibration by Lot** from the menu.
2. Select the appropriate method to be reviewed.
3. Review the Acceptance Criteria Details to determine which criteria failed.
4. Press Show Details.
5. If configured criteria fails, then:
   a. Check the volume and expiration date of the current calibrators onboard and rerun the calibration one more time. If failure continues proceed to next step
   b. Check the reagent inventory for that specific method, 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. Now rerun the calibration using a new set or different lot number of Calibrators.
   c. If a calibration is pending for review due to the QC failure, then check the volume and expiration date of the QC bottle onboard. Pour fresh QC if needed and repeat. Once QC is within acceptable ranges go to **System > Method Summary > Calibration > Accept/Reject Calibration** to accept the calibration. Enter a comment on what's been done and why Calibration is accepted. Now 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 as a proof that the QC was repeated and is acceptable.
   d. If failures continue, contact the Siemens Technical Solutions Center.

G. 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.

1. From the Calibration menu, select **Calibration by Lot**.
2. Use the twin selector to designate left or right instrument (Dimension Vista® 1000T only).
3. Select a reagent lot.
4. From the lower Actions menu, select **Cancel Order**.

H. 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 calibration is run automatically; the instrument will automatically run QC after calibration.
- The instrument will automatically print the calibration report.
- To print the 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.

I. IMT Calibration

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

J. Manual IMT Calibration (This procedure is instrument specific and needs to be performed on the left and right sides of a Dimension Vista® 1000T System.)

1. Press **System > IMT Calibration**.
2. Press **Calibrate IMT**. The Calibrate IMT button changes to gray and is unavailable when the IMT system is busy.

K. Calibration Schedule

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).

- 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 Operational/Maintenance 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

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)

Dimension Vista Calibrator Guide

Once the cap of a calibrator is removed, that calibrator set must not be used on board the Dimension Vista System.

Calibrator	Reagent	Cal. Storage Temp.	Calibrator Stability when in use
A1C CAL	HbA1c	2 - 8º C	Reconstituted Cal. is stable for 8 hours at 25º C & 48 hours at 2 - 8º C
ALP CAL	ALP	2 – 8º C	Once opened, Calibrator is stable for 7 days on board Vista, & 30 days off board when stored at 2 - 8º C.
BHCG CAL	BHCG	2 – 8º C	Once opened, Calibrator is stable for 7 days on board Vista, & 30 days off board when stored at 2 - 8º C.
BILI CAL	TBIL, DBIL	2 – 8º C	Once opened, Calibrator is stable for 14 days on board Vista, & 14 days off board when stored at 2 - 8º C.
CTNI CAL	CTNI	-20 to -10º C	Once opened, Calibrator is stable for 7 days on board Vista, & 7 days off board when stored at 2 - 8º C.
MMB CAL	MMB	2 – 8º C	Once opened, Calibrator is stable for 7 days on board Vista, & 30 days off board when stored at 2 - 8º C.
MYO CAL	MYO	-20 to -10º C	Once opened, Calibrator is stable for 7 days on board Vista, & 30 days off board when stored at 2 - 8º C.
CHEM 1 CAL	BUN, CA, CHOL, CREA, GLU, LA, MG, UA	-25 to -15º C	Once opened, Calibrator is stable for 1 day on board Vista, & 7 days off board when stored at 2 - 8º C.
CHEM 2 CAL	PHOS, SAL, TRIG	2 – 8º C	Once opened, Calibrator is stable for 1 day on board Vista, & 30 days off board when stored at 2 - 8º C.
CHEM 3 CAL	CO2, ETOH, AMON	2 – 8º C	Once opened, Calibrator is stable for 1 day on board Vista, & 30 days off board when stored at 2 - 8º C.
CHEM 4 CAL	ALB, TP	2 – 8º C	Once opened, Calibrator is stable for 7 days on board Vista, & 31 days off board when stored at 2 - 8º C.
PROT 2 CAL	CRP	2 – 8º C	Once opened, Calibrator is stable for 12 days on board Vista.
DRUG 1 CAL	LI, PHNO, PTN, THEO	2 – 8º C	Once opened, Calibrator is stable for 15 days on board Vista, & 31 days off board when stored at 2 - 8º C.
DRUG 2 CAL	ACTM, CRBM, GENT, TOBR, VALP, VANC	2 – 8º C	Once opened, Calibrator is stable for 15 days on board Vista, & 31 days off board when stored at 2 - 8º C.

Calibrator	Reagent	Cal. Storage Temp.	Calibrator Stability when in use
DRUG 4 CAL	DIG	2 – 8º C	Once opened, Calibrator is stable for 14 days on board Vista, & 31 days off board when stored at 2 - 8º C.
ENZ 1 CAL	AMY, GGT, LIP	2 – 8º C	Once opened, Calibrator is stable for 7 days on board Vista, & 30 days off board when stored at 2 - 8º C.
ENZ 2 CAL	ALTI, AST	2 – 8º C	Once opened, Calibrator is stable for 7 days on board Vista, & 30 days off board when stored at 2 - 8º C.
ENZ 5 CAL	LDI	2 – 8º C	Once opened, Calibrator is stable for 7 days on board Vista, & 30 days off board when stored at 2 - 8º C.
ENZ 6 CAL	CKI	-20° C or colder	Once opened, Calibrator is stable for 7 days on board Vista, & 7 days off board when stored at 2 - 8º C.
LIPID CAL	HDLC	- 20° C or colder	Once opened, Calibrator is stable for 7 days on board Vista, & 30 days off board when stored at 2 - 8º C.
IRON CAL	IRON	2 – 8º C	Once the ampule is opened, it should be used immediately and any portion not used should be discarded.
LOCI CAL	FT4, TSH	-25 to - 15° C	Once opened, Calibrator is stable for 7 days on board Vista, & 30 days off board when stored at 2 - 8º C.
TIBC CAL	TIBC	2 – 8º C	Once opened, Calibrator is stable for 7 days on board Vista, & 31 days off board when stored at 2 - 8º C.
UCFP CAL	UCFP	2 – 8º C	Once opened, Calibrator is stable for 7 days on board Vista, & 31 days off board when stored at 2 - 8º C.
UDAT CAL	AMPH, BARB, BENZ, COC, OPI, PCP, THC	2 – 8º C	Once opened, Calibrator is stable for 15 days on board Vista, & 31 days off board when stored at 2 - 8º C.

Quest Diagnostics

☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital

Dimension Vista Calibration List

Requested by: _____ Department: Chemistry

Date Calibration Request posted	Date Calibration performed	Vista 1 Analytes	Vista 2 Analytes	Vista 3 Analytes (SGAH only)	Recalibration * Current Lot, Include Lot #	New Lot / Correlation, Include Lot #	Tech Code

*Recalibration of current lot must be done within 48 hours

Comments: _____

_____

_____

QDX TEa List

New Reagent Lot or Shipment Comparison Study Form

QUANTITATIVE RESULTS

Instructions: *Fill in all blue sections.*

NOTE: *QC are required for all New Ship Dates, whereas QC **plus** patient's samples are required for lot changes.*

Analyte:

	Reagent Name	Vendor	Lot #	Received Date	PIU Date (Optional)	Expiration Date (Optional)	Packet Insert Version/Date
Current							
New							

Allowable Total Error

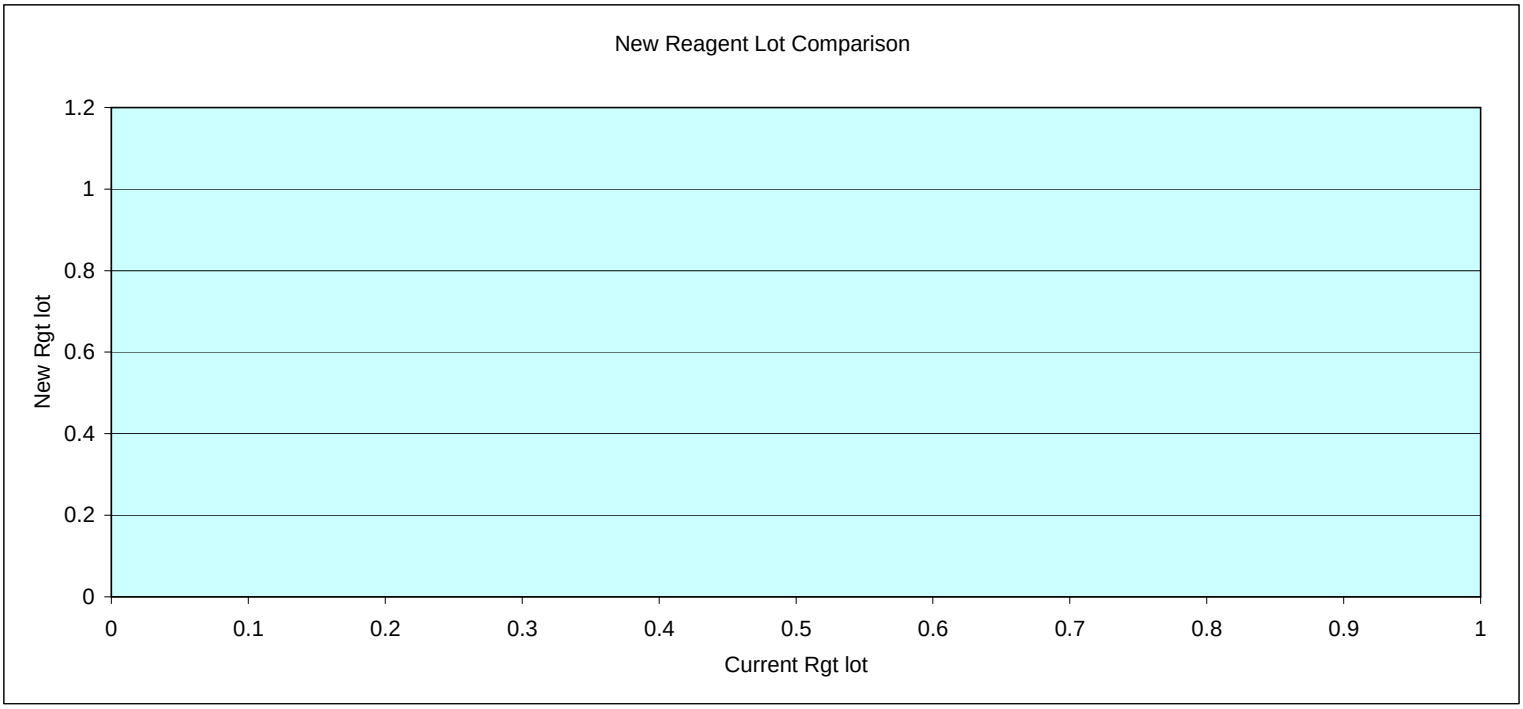
TEa (percent):		%
TEa (units):		

Sample #	**Inst ID:**		
	Sample ID	Old Reagent	New Reagent
Patient 1			
Patient 2			
Patient 3			
Patient 4			
Patient 5			
Patient 6			

Count	0	0
Mean	#DIV/0!	#DIV/0!
Bias %:		#DIV/0!
Bias units:		#DIV/0!
TEa/4 in %:		0.000%
TEa/4 in units:		0.000
Estimate of Bias:		#DIV/0!

			Difference for Individual Samples	
Reference Value	Minimum Acceptable	Maximum Acceptable	Low Limit Evaluation	High Limit Evaluation
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept

	Old Reagent		New Reagent		
	Mean	SD	New Lot Value	SDI	OK?
QC1					
QC2					
QC3					
QC					
QC					



Individual difference: Difference between results with old and new reagents must not exceed the allowable total error (TEa) for the assay.

Estimate of Bias: Mean value for the new reagent must not vary from the old reagent by more than one fourth of the TEa.

QC results: QC results for new reagent lot should fall within range for old lot of reagent.

If above criteria are not met (indicated in red), please review data with director before releasing results.

Comments:

Tech: **Date:** **Technical Director (or Designee)** **Date:**