Name Jagannath Choudhary
Department Healthcare – Service
Telephone +91-022 3370 0725
Fax +91-022 3370 0654
Mobile +91- 09769108282
E-mail Jagannath.chouchary@siemens-healthineers.com

CALIBRATION CERTIFICATE

This is to certify that Dimension EXL 200, Equipment ID: 1042762920 & serial number DE271193 installed at MAEER's Vishwaraj Hospital Laboratory has been successfully calibrated on January 6 ,2022. Please find below, results of calibration performed on the instrument.

Please find below, results of calibration performed on the instrument.

Photometric Calibration Data are as follows:

Parameter	Result	Acceptable Ranges
Photometer Dark Calibration		
Reference	9266.29 Hz	8500 – 11000 Hz
Sample Outer ON	9448.72 Hz	8500 – 11000 Hz
Sample Outer OFF	9444.90 Hz	8500 – 11000 Hz

Lamp Calibration		
Low Calib Level	52.4%	NA
High Calib Level	58.2%	NA
Photometer Arm Alignment	-5%	-2 to -9

Filters	Offset (mAU)	System Check Results	Range
293 nm	292	0.44	+/- 2.5
340 nm	323	0.29	+/- 1.5
383 nm	336	0.24	+/- 1.5
405 nm	325	0.18	+/- 1.5
452 nm	322	0.24	+/- 1.5
510 nm	300	0.27	+/- 1.5
540 nm	309	0.37	+/- 1.5
577 nm	307	0.34	+/- 1.5
600 nm	302	0.23	+/- 1.5
700 nm	306	0.26	+/- 1.5

System Check Results – CHK Lot No: BB2075

Parameters			Range	
	Mean	SD	Mean	SD
Reagent 1	398.00	1.65	392+/-15	< 3.8
Reagent 2	399.53	1.89	392 +/-15	< 3.8
Sampler	39.80	0.24	39.0 +/-2	< 0.8

Temperature		
Cuvette	37.0°c	37.0°c +/- 0.2
Regent Tray	4.2°c	2°c to 8°c
HM	43.0°c	43.0°c +/- 1.0

The instrument is working satisfactorily, subsequent to Calibration of the above parameters, and the next PM is due on July 2022

Next Calibration is due in the month of July 2022

Note: CHK kit is an USFDA approved kit used in performing the system check in all Dimension systems. The carton value is a predetermined value for which the limits are defined in system check screen and operator guide of Dimension.

Siemens Healthcare Private Limited

Jagannath Choudhary
Regional Customer Care Manager – West & West Central

Instrument Installation Acceptance Statement

Account Name: "MAEER's Vishwaraj Hospital Laboratory, Rajbaug, Pune-Solapur Road, Loni Kalbhor,

City: Pune-412201 State: Maharashtra

Instrument Installed: Dimension EXL 200 S/N: DF271193

S/N:

S/N:

Install Completion Date: 19th July 2019

Customer:

I understand and state that the installation of the Dade Behring instrument(s) has/have been completed to my satisfaction, including training of laboratory personnel on the operation and maintenance of this instrument(s).

I also state that the instrument(s) is/are (1) operating in accordance with manufacturing specification and (2) the instrument(s) and consumable(s) performance has/have been validated according to Dade Behring's protocol.

Customer's Name: Dr. Aniruddha Garud
Print Name

Customer Signature: Date: 19/07/2019

Dade Behring CAS:

CAS's Name: Mr. Nitin Deshmukh
Print Name

CAS Signature: Date: 19/07/2019

RightFax (302-631-7259) a copy of this Customer Acceptance Statement within 2-3 business days of completing the installation to the Installation Coordinator in Glasgow, DE.

THIS PAGE FOR INTERNAL USE ONLY

Instrument Installation Procedure
Dimension® EXL™ clinical chemistry system

NOTE: It is recommended to install the RMS module hardware and electrical modules before continuing with the installation of the instrument.

1. PURPOSE AND SCOPE

This document describes how to install the Dimension® EXL™ Clinical Chemistry System

2. INVENTORY/UNPACKING

- ❑ 2.1 Visually inspect instrument for shipping damage.
- ❑ 2.2 Remove packaging material (foam, tape, tie wraps, etc.) from instrument. Discard packing material according to local area standards or procedures.
- ❑ 2.3 Inventory all items received and verify against the shipping list.
  - Instrument
  - Consumables
  - System Materials Manual (includes items such as the Accessory Kit, *Using and Maintaining Dimension® EXL™ Manual*, *MSDS Manual*, and sample wheel segments)
  - Monitor box (including articulating arm, monitor tray, keyboard, and printer)
  - UPS
  - Bump stop kit
  - QCC PowerPak barcode reader, USB Key

3. PARTS AND CONSUMABLES INSTALLATION

- ❑ 3.1 Install the monitor.

  Install the monitor articulating arm on the Dimension® EXL™ instrument. Route the monitor video, power, and touch cable through the monitor arm. Connect the monitor power cable to extension cable inside the instrument. Route the monitor video cable and touch cable through the monitor arm with the cable clamps provided and through the instrument right side behind the cabinet side panel. Connect the monitor video cable to the computer video port and the touch cable to the rocket port serial card port one.

See Figures 1, 2 and 3 for proper routing of the cables.

Figure 1:

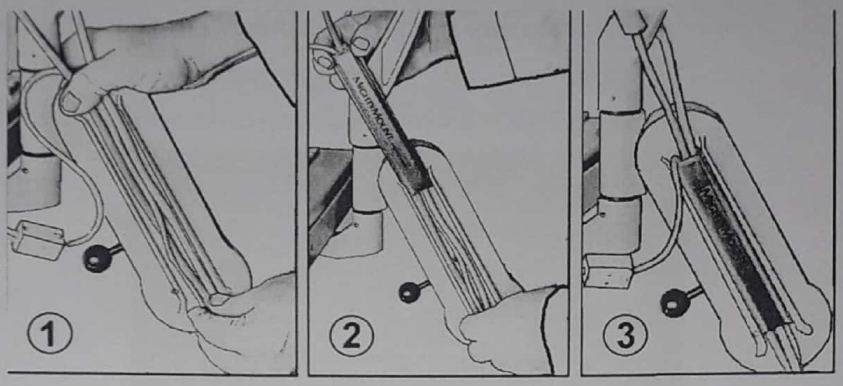


Figure 2.

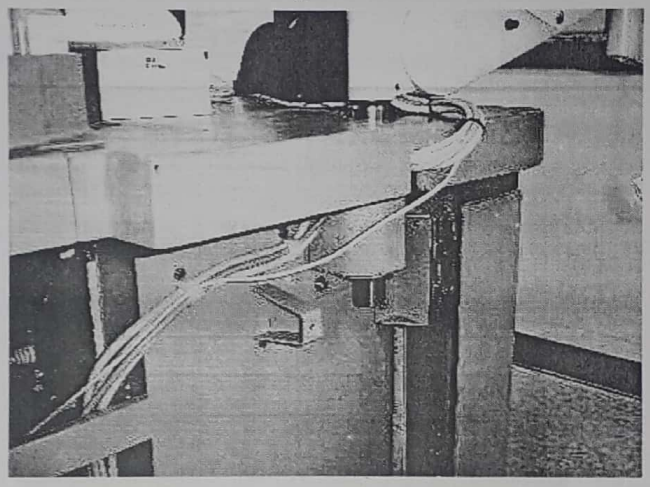
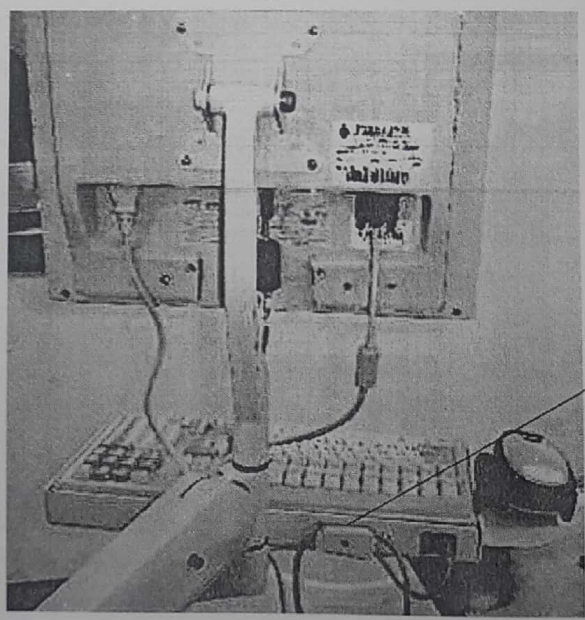


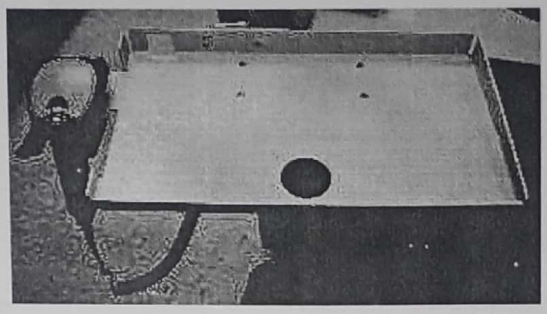
Figure 3



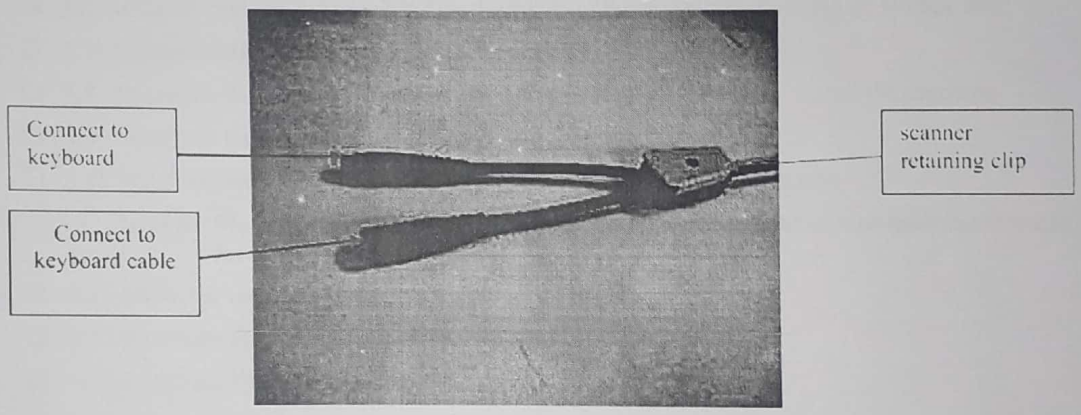
❑ 3.2 Install UPS, refer to Installation procedure at back of this section.

❑ 3.3 Install QCC PowerPak barcode scanner

Place the barcode scanner into the holder at the left of the keyboard .



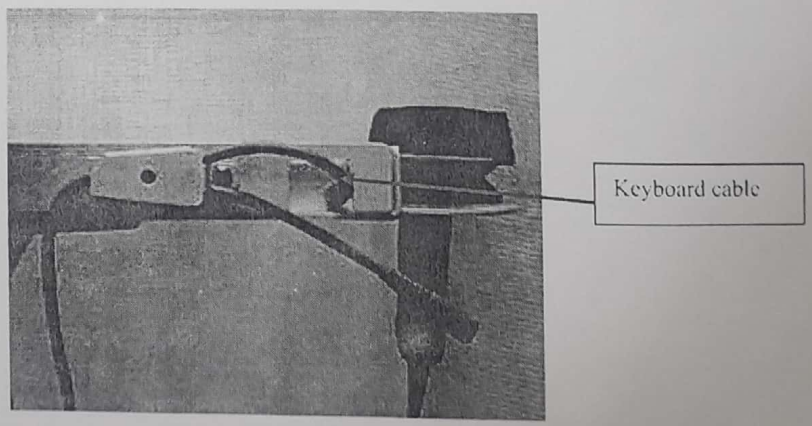
Place barcode scanner cable block inside of scanner retaining clip and attach clip to the keyboard tray.



Connect one connector from the barcode scanner to the existing keyboard cable.

❑ 3.4 Install the keyboard.

Feed other connection of the barcode scanner through the hole in the back of the keyboard tray and connect to the keyboard using the screws and cable retaining clip from step 1.



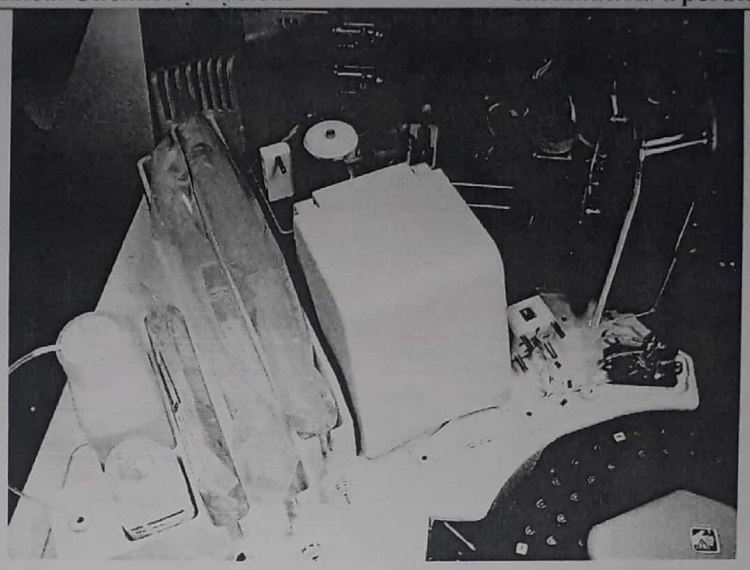
Place keyboard back into keyboard tray.

- ❑ 3.5 Give the USB drive to the customer, this drive will be used to store calibration, QC and patient data. Instruct the customer to install USB drive into a USB port on the front of the computer when needed.
- ❑ 3.6 Install the XLink warning label on the inside of the glove box cover (spare storage lid).
- ❑ 3.7 Configure the sample tube bar code readers for ASTM, if necessary.
- ❑ 3.8 Install the bar code labels on the sample wheel segments, and then install the segments.
- ❑ 3.9 Install the backup disk in the floppy drive.
- ❑ 3.10 Install the spent cuvette waste container and the chemistry waste bottle.

  NOTE: Make sure the lid on the chemistry waste bottle is tight so a proper vacuum can be formed.

- ❑ 3.11 Install the cuvette film canister and new diaphragm.
- ❑ 3.12 Install the Dade Behring Inc. Water Diluent bottle.
- ❑ 3.13 Install the IMT Consumables.

Place the Standard A, Standard B, and Flush bags in their color-coded compartments in the IMT area. Position the QuikLYTE® Sample Diluent and Salt Bridge Solution bottles in their holders.



IMT Tubing

The IMT Installation Tubing Kit (766286) contains:
- 766722.901 (3x)
- 766771.901
- 766777.901

It is inside the cuvette waste container in the System Material Kit box.

Install the tubing according to the diagram on the IMT lid. Be sure to remove the small plastic caps covering some of the connectors.

NOTE: The D1 and D2 tubing in the installation kit (766286) are not needed. They are left "in place" during the manufacturing pack-up process.

Put two extra "X" pump tubes in the accessory spare parts kit.

NOTE: X3 line comes with 1-in (2 mm) connection tubing on the end. There is also a connection tubing on the "T" it connects to, so discard one of these duplicate tubes.

The kit contains the following factory-installed extra parts:

- sample diluent bottle cap
- IIMT waste line
- D2 and D1 tubing

NOTE: Make sure the Diluent cap is installed on the Diluent bottle.

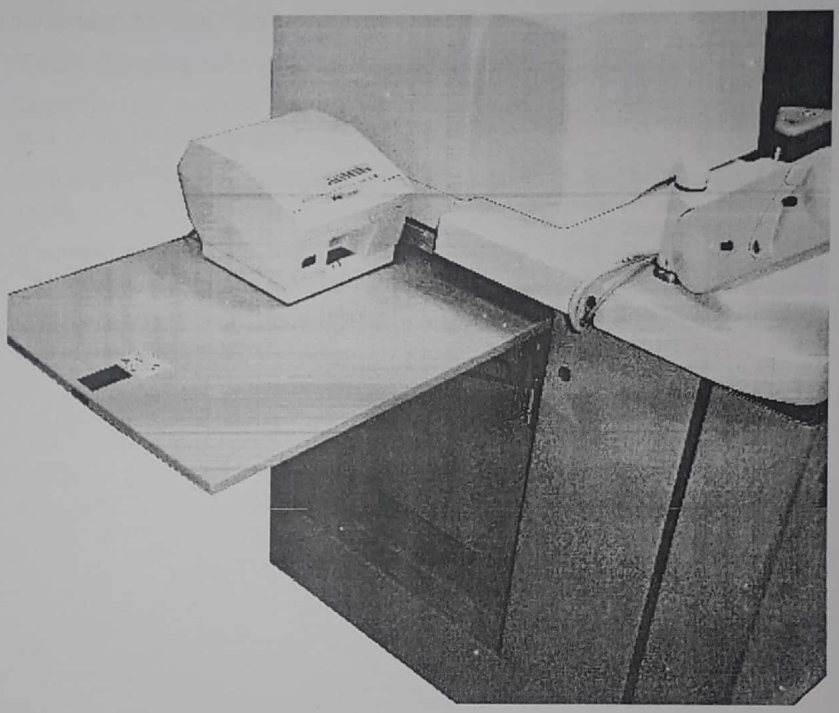
- Salt Bridge Solution
- QuikLYTE® Integrated Multisensor

NOTE: Installing the wall spacers are extremely important. DO NOT SKIP.

- ❑ 3.14 Install the two wall spacers.
- ❑ 3.15 Install HM consumables (vessels, chemistry wash, probe cleaner, vessel waste container, and sample probe cleaner).

❑ 3.16 Install the system printer

1. Unpack the printer, USB cable and power cables from the printer box
2. Pull out the printer shelf on the left hand side of instrument
3. Place printer on shelf and connect USB cable to printer and USB port on back of instrument
4. Install power cable from back of printer to extra receptical (either on the UPS or Y-connector out of UPS)
5. Install a roll of paper in the printer



❑ 3.17 Update the Spare Parts Kit:

a. Remove the spare parts zip lock bag (PN 766704) from the instrument cabinet door. Place the parts in the drawers according to the "In the box" procedure No. 703705.604 packed with the instrument.

b. Remove the Read/Right antistatic pads from the Static Stopper box and place them in drawer no. 12.

❑ 3.18 Replace the current customer spare parts reorder list with the new one (PN 730705.604); the new list reflects the changes or additions that were made to the spare parts accessory kit.

4. **MECHANICAL CHECKS (Power Off)**

❑ 4.1 Verify that all circuit boards are secure.

❑ 4.2 Verify that all connections to backplane board are secure. To check connectors, remove the two fans on panel (four screws) from back of instrument.

5. POWER LINE CHECKS

❑ 5.1 Check the wall outlet with DVM and record the voltages on the page titled **"EM Specification & Verification"** page.

6. VOLTAGE CONFIGURATION

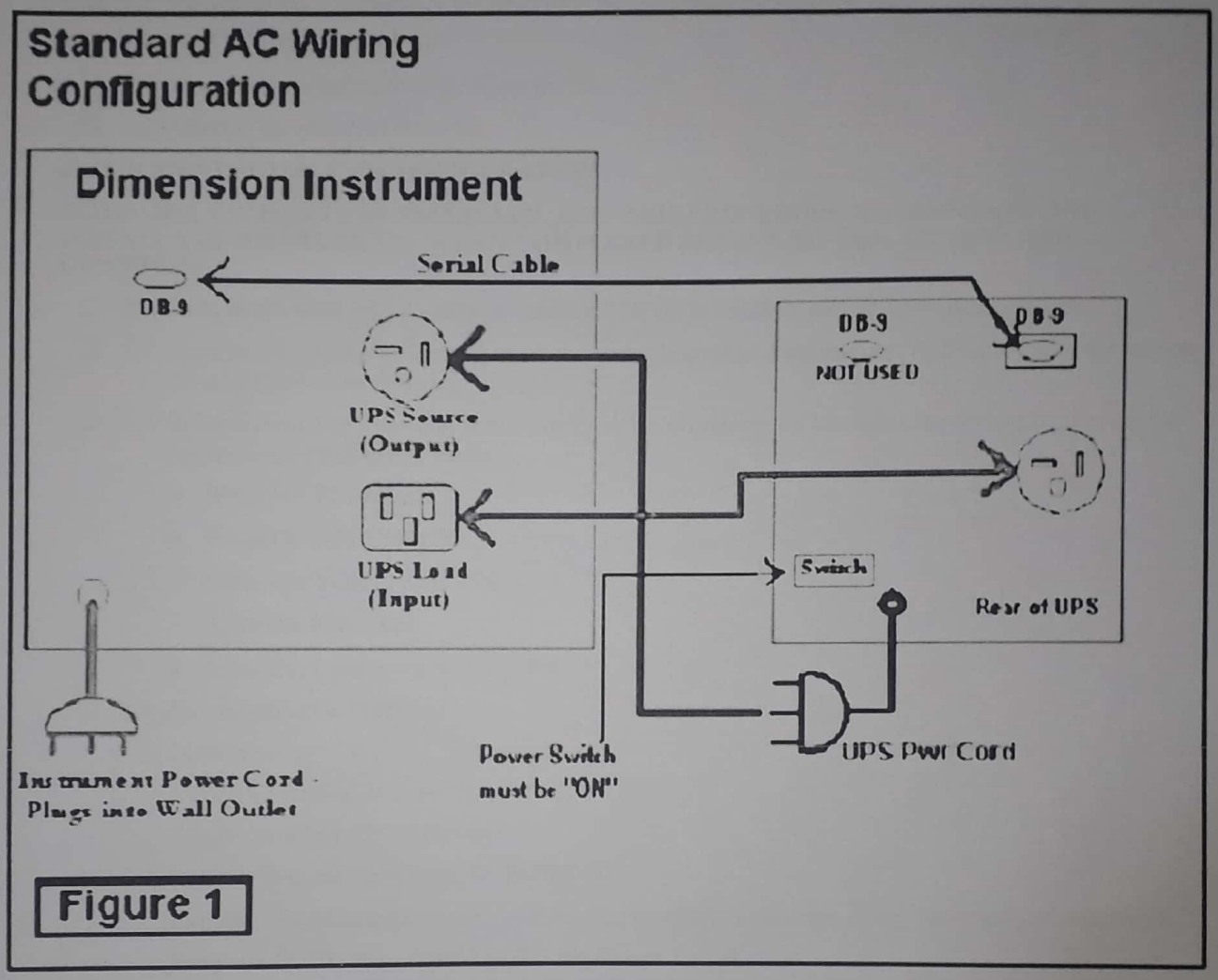
❑ 6.1 Install the UPS using the following steps:

NOTE: The Falcon model utilizes an added communication relay card with a DB-9 connector for correct serial communications. The standard DB-9 connector on the back of the UPS must not be used.

Standard AC Wiring Configuration

Very Important! You must perform the first four steps before installing the UPS.

1. Ensure the voltage dip switch settings on the rear of the UPS are set up for 120 volts.
2. Insert the large external fuse (tie-wrapped to the rear UPS fan) into the fuse holder located on the rear of the UPS on the right side above the receptacles.
3. If this is a UPS replacement, shut down the instrument, turn off the existing UPS, and unplug the cords.
4. To install the new UPS, make serial cable and power cord connections as shown in **Figure 1 – "Standard AC Wiring Configuration"**.
5. Turn on the UPS. For UPS functions and features, reference the respective UPS users manual that comes with the UPS.



- ❑ 6.2 Turn ON the UPS.
- ❑ 6.3 Ensure power is supplied to the instrument and all cables are connected.

7. **WATER/WASTE INSTALLATION**

- ❑ 7.1 Connect the instrument to the water purifier.
- ❑ 7.2 Connect the plumbed waste line.

8. **INSTRUMENT SETUP AND CONFIGURATION**

NOTE: IF AN RMS IS TO BE INSTALLED, EXIT THIS PROCEDURE AT THIS POINT AND INSTALL THE RMS MODULE. WHEN COMPLETED RETURN TO THIS SECTION AND CONTINUE.

- ❑ 8.1 Turn on the main instrument power switch. If RMS is installed, turn on RMS power switch.
- ❑ 8.2 Turn on the monitor power and adjust the screen brightness and intensity. Refer to the monitor manual for adjustment instructions.
- ❑ 8.3 In the System Configuration Menu, configure the instrument for the following options by moving the cursor down and pressing **Enter:**
  - Water In – PLUMBED
  - Waste Out – PLUMBED
  - Automatic Vessel Load – ON
  - Automatic HM – ON
  - Automatic Cartridge Removal – ON
- ❑ 8.4 Decontamination Procedure:

  Needed:

  1 2L50A Selective Micro® Clean, PN 286072.001

  Adapter coupling, PN 256761.001

  Chlorine Dioxide Test Strips, PN 268080.001

  Purpose: To decontaminate the instrument at installation and when doing preventative maintenance.

  Reagents: 2L50A bag of *SELECTIVE MICRO®* CLEAN.

  NOTE: The steps of this procedure are specific for the Dimension® RxL/RxL Max™/EXL™, Dimension® XL and Dimension® ARx Software.

- ❑ 8.4.1 Disable the water system supply:
  - From the Operating menu, press F6: System Config.
  - Use the arrow keys to move the cursor down to the "Water In"
  - Change from "Plumbed" to "Manual"
- ❑ 8.4.2 Prepare *SELECTIVE MICRO®CLEAN* following instructions on bag. **NO NOT USE TAP WATER.**
- ❑ 8.4.3 Decontaminate the water and chem wash system.

a. Pour off approximately 0.5 liters of the SELECTIVE MICRO®CLEAN solution into an empty chemistry wash bottle and install this chemistry wash bottle back onto the instrument.

b. Pour off approximately 0.5 liters of the SELECTIVE MICRO®CLEAN solution into a small bottle or container to be used to decontaminate the supply line. (The white supply tubing will hold 8.1 ml/ft)

c. Remove and empty the water bottle. Pour the remainder of the SELECTIVE MICRO®CLEAN, approximately 1 liter, into the empty water bottle.

d. Install the water bottle with the remaining SELECTIVE MICRO®CLEAN solution back on the instrument and secure the cap assy.

e. Go to main menu and press F4: SYSTEM PREP, then F7: PUMP PRIME. Set CYCLES to 10.

f. Press F1: PRIME WATER to pump SELECTIVE MICRO®CLEAN solution through the system.

g. Press F5: IMT MONOPUMP

h. Press F6: HM

i. Press F1: HM WASH PUMP to pump SELECTIVE MICRO®CLEAN solution through the chem wash system. (Do the HM WASH PUMP an additional 5 cycles) Ensure some fluid remains in the bottle after the pump cycles.

Allow the solution to remain in the system for a **MINIMUM** of 15 minutes. If this is the first time, CL02 has been used in this instrument, allow the CL02 to remain in the instrument for 45 minutes. (Prime all pumps (f – i above) an additional 5 cycles at the 10 minute mark.)

NOTE: You can continue on with step 8.5.4 as soon as you complete above steps.

❑ 8.4.4Decontaminate the Water Supply Line

WARNING:	If multiple instruments are connected to the feed line, ensure lines are disconnected from any instrument not being decontaminated to prevent *SELECTIVE MICRO®CLEAN* contamination. These lines should be flushed well prior to reconnection to the instruments.

a. From main menu press F7: DIAGNOSTICS, press F1: ELECTRO/MECH, then press F6: WATER WORKS.

b. Press F4: VACUUM ON/OFF twice to turn the vacuum pump off. This will prevent fluid from being aspirated into the vacuum pump, when the waste pump line is removed from the waste bottle.

c. Disconnect "Waste Out" quick-disconnect connector from the top of the waste bottle. Connect it to the mating connector of the adapter coupling (PN 256761.001).

NOTE: An adapter coupling is required for each instrument being decontaminated

d. Disconnect the water inlet tubing from the water bottle cap. (Press and hold the ring down while pulling the tubing from the connector.)

e. Connect the water inlet tubing to the remaining connector of the adapter coupling. Ensure tubing is securely pressed in.

f. Put the millipore unit into STBY mode or turn off the water supply.

g. Disconnect the supply tubing from the water system.

h. Insert the end of this tubing into the bottle containing the SELECTIVE MICRO®CLEAN solution.

i. At the water works menu:

1. Press F1: WATER ON/OFF to turn the water valve on.
2. Then press F2: WASTE ON/OFF to turn the waste pump on. *SELECTIVE MICRO®CLEAN* solution will be drawn into the tubing.
3. Repeat steps 1 and 2 until the tubing is filled up to the adapter **Do not allow the bottle to pump empty.**
4. Press F2: WASTE ON/OFF again to turn off the waste pump.

Allow the solution to remain in the system for a **MINIMUM** of 15 minutes.

❑ 8.5 Rinse *SELECTIVE MICRO®CLEAN* solution from the water supply line:

j. Remove the supply tubing from the *SELECTIVE MICRO®CLEAN* solution.

k. Press F1: WATER ON/OFF to turn the water valve on.

l. Then press F2: WASTE ON/OFF to turn the waste pump on to purge air through the tubing.

m. Reconnect water supply tubing to the Millipore system

n. Put Millipore back on line

o. Disconnect the waste tubing from the adapter and reconnect it to the waste bottle.

p. Disconnect the water bottle tubing from the adapter and reconnect it to the water bottle.

q. Press F1: Water ON/OFF to turn the water valve on.

r. Allow water bottle to fill (You may have to press F1 a few times for this to happen) DON'T ALLOW WATER BOTTLE TO OVER FILL

s. Exit to the operating menu.

❑ 8.6 Rinse the water and chem wash systems:

a. Remove the water and chemistry wash bottle lids and float switch assemblies and set them into spare bottles (or on a clean paper towel if a bottle is not available).

b. Discard the contents of each bottle and rinse each bottle with deionized water.

c. Fill the bottles with deionized water and install the lid assembles.

d. Agitate each bottle gently to rinse the bottom of the lids and the float switch assemblies.

e. Cycle water through the system as described in step 8.4.3: e, f, g, h, & i.

f. Repeat steps a-e.

g. Check for *SELECTIVE MICRO®CLEAN*, with test strips, at Wash Probe 1 and R2 by pulling tubing off probes and cycling associated pumps. Collect water in a test tube. Test strips only need 5 seconds of contact with water.

❑ 8.7 Reassemble the water and Chemistry wash systems:

a. Install the water bottle and lid assembly on the instrument.

b. Change the "Water In" back to "plumbed", as described in step 8.3 and allow the system to fill the water bottle.

c. Install a new Chemistry Wash bottle and update the count.

d. Perform another system prime as described in Step 8.4.3, e, f, g, h, & i.

Set cycle count back to 3 when finished.

❑ 8.8 From the System Counters screen, select the clean probe routine. Condition the photometric sample probe by using a normal serum sample for the fluid.

❑ 8.9 Connect the phone cable from the modem (at the back of instrument) to the phone jack on the wall. Label this phone jack connection for proper identification. Verify proper operation of the modem by contacting the Technical Assistance Center for remote access of the instrument.

❑ 8.10 Record the modem phone number on the "Installation Rating" form.

❑ 8.11 Set the instrument identification, date/time, and report title.

❑ 8.12 Reset the cuvette, diaphragm, and aliquot wheel counts.

❑ 8.13 Update the HM consumable counts:

- Wash Buffer
- Vessels
- Sample Probe Cleaner

- Reagent Probe Cleaner

❑ 8.14 Configure the system for the customer's bar code label format. Use "Autodiscriminate" only if multiple types of bar code labels are used.

9. SYSTEM AND ALIGNMENT CHECKS

❑ 9.1 Use the Electro/Mech diagnostics routine for the photometer. Press **F4: Initialize** and cycle the photometer to check for correct operation.

❑ 9.2 Load the film. Observe the cuvette formation. The pressure gauge should read 2-6 psi during the heating period and then jump up to at least 18 psi and not drop below 15 psi during cuvette formation. After the cuvette is formed, the pressure gauge should read close to 0 psi.

NOTE: During the heating period, the flowmeter should read 4.0 – 9.0 L/min.

❑ 9.3 Record Gaps listed on "**EM Specification & Verification**" page. Adjust if out of specification.

❑ 9.4 Perform the following alignments:

- Automatic Flex™ Loader
- Sample Area – including Barcode alignments, Sample Tube and SSC maximum depth alignments
- Reagent Area
- HM Area
- RMS (If equipped)

❑ 9.5 Perform the following photometer alignments/calibrations.

- Dark Current calibration
- Lamp calibration
- Photometer alignment
- mAU Offset calibration

❑ 9.6 Perform a mixer calibration:

a. Go to the HM Module Alignments screen. From the Operating Menu, press:
F7: Diagnostics
F3: Alignments
F6: HM Module

b. Press **F5: Mixer Calib.** The instrument will perform the mixer calibration and will prompt you when it is finished.

❑ 9.7 Calibrate the cuvette and reagent temperatures.

NOTE: The Dimension® EXL™® should be turned on, flexes loaded, with all sides and shields in place, for at least two hours before measuring temperatures.

❑ 9.8 Calibrate the HM incubate wheel temperature

NOTE: The acceptable temperature range for the incubate wheel is 42.0° C – 44.0°C (default is set to 43.0°C).

10. SYSTEM PREPARATION

❑ 10.1 Enter ABS carton Value: on the Daily Maintenance Screen

❑ 10.2 Enter the reference and assay ranges, and coefficients for LYTES. To do this:

a. Go to the Main Operating Menu and press **F6: System Configuration.**

b. Enter the system password as prompted.

c. Press the LYTES test key.

d. Enter the ranges and coefficients for the Na (see ranges and coefficients below).

e. Press F4: Store Param's.

f. **Press F1: Next Method** to display parameters for K.

g. Repeat the above steps for each electrolyte.

Reference Ranges & Coefficients	Na	K	CL	ECO2	Urine CL
Reference Ranges for:					
Serum / Plasma	136-145	3.5-5.1	98-107	21-32	NA
Urine	40-220	25-125	110-250	NA	NA
Assay Ranges for:					
Serum / Plasma	50-200	1-10	50-200	5-45	NA
Urine	5-300	1-300	10-330	NA	NA
Coefficients:					
C0	1.5	-0.2	-10.0	0.0	0.0
C1	1.01	1.05	1.09	1.0	1.06

❑ 10.3 Prime water from pump prime screen with 10 cycles. Reset to 3 after cycle prime.

❑ 10.4 Add an ABS flex reagent cartridge to the reagent tray and schedule a System Check.

Do three consecutive System Checks – all three must pass. Attach printouts to the System Check form.

Acceptable results are listed below:

Test	Performance Limits (mAu)
HM, mean	10% of the value on the ABS carton flap ± 4 mAu
HM, SD	≤ 1.6 mAu
RMS, SD	≤ 3.8 mAu

❑ 10.5 Configure the indirect IMT system and update the IMT consumable screen. Process 2-3 conditioning samples.

❑ 10.6 Record the data and attach the Indirect IMT calibration printout to the IMT Data form.

❑ 10.7 Run a DILCHK until specifications are met (SD: NA ≤ 1.4, K ≤ 0.04, bias ± 1.0%). Record data and attach printout to the Dilution Check (DILCHK) form.

❑ 10.8 Cascade hydrated stability and TSH sensitivity Day 1. Prime all HM fluids from the pump prime screen. Perform the cascade hydrated stability and TSH sensitivity tests as follows. Record data and attach printouts to the TSH, MCAS, CRQC Results form.

NOTE: The FSE performs TSH Day 1 and Day 2 testing on consecutive days following the procedure below. Perform Day 2 within 20 to 28 hours after Day 1. The Day 2 procedure is located after the MCAS and the CRQC Data Sheets in this section. Attach printout sheets to installation manual pages for the CAS to review.

Materials and Reagents Needed:

- TSH Flex™

- 1 Bottle of Level 1 THY Calibrator
- 1 Bottle of Level 3 THY Calibrator

NOTE: Use Chem wash for L1 THY calibrator if necessary.

a. Load 2 TSH Flex® reagent cartridges onto instrument.

b. Hydrate the 2 TSH reagent cartridges.

From the main op menu

1. Press F4 System Prep
2. Press F2 Reagent Setup
3. Press F7 Request by Lot
4. Use the arrow key to cursor to the TSH No. of tests to hydrate field
5. Type 50 tests per flex and press enter
6. Press F4 Hydrate

c. Change the TSH method configuration as follows:

1. From the Operating Menu press **F6: System Config,** then **F1: Method Parameters.**
2. Press Enter and then press **Alt / TSH** (TSH Method).
3. Press **Alt / P** to get a screen print of the method parameters. **Save** this printout for the CAS who will need to reenter these parameters.
4. Press **F8: Next CALC'N** to change the calculation to **"Linear."**
5. Press **F7: Set mAU** and answer **Y** (yes) when you are asked, "Do you really want to set this method to mAU?"
6. Press **F3: Next Unit** until "mAU" is displayed in the Result units field. (Selecting mAU units will allow the TSH method to process without first calibrating it.)
7. Enter an assay range of 0 – 50 in the urine column. [NOTE: if this field is left blank (XXXX), incorrect fluid type errors will be generated]
8. Press **F4** to store the parameters and return to the Operating Menu.

d. Schedule TSH Assays using the Level 3 THY Calibrator:

1. From the Operating Menu press **F1: Enter Data.** Enter the position of sample cup. Enter the patient name as **Level 3 THY Cal** and sample number as **UQC2.**
2. Change the mode to **Sample Cup**, the priority to **QC**, and the fluid to **Urine QC2**.
3. Enter six TSH replicates (press **Alt / TSH** six times).
4. Put 1.0 mL of THY Level 3 Calibrator in a sample cup and place it in the designated sample cup position.

   NOTE: Save this bottle of THY Level 3 calibrator (refrigerate) as it will be used during Day 2 testing.
5. Press F2: Process Single

   NOTE: Perform step e. immediately after step d. (Level 3 must be run before Level 1)

e. Schedule TSH Assays using Level 1 THY Calibrator:

1. Enter the position of the sample cup. Enter the patient name as **Level 1 THY Cal** and sample number as **UQC1**.
2. Change the mode to **Sample Cup**, the priority to **QC**, and the fluid to **urine QC1**.
3. Enter ten TSH replicates (press **Alt / TSH** ten times)
4. Put 1.0 mL of Level 1 THY Calibrator in a sample cup and place it in the designated sample cup position.
5. Press **F2: Process Single**
6. Repeat steps 1 through 5 for 10 additional tests from a 2nd cup. (DO NOT attempt to run all 20 tests from 1 cup!)

f. Analyze the data.

When the run is complete (about 35 minutes), review the mAU results from the printout for the two sets of Level 1 THY Calibrator results and the one set of Level 3 THY Calibrator results.

Acceptable results using the THY Calibrator are listed below:

Test	Performance Limits (mAU)
Level 1 THY Calibrator; mean	-15 to +25
Level 1 THY Calibrator; SD	≤ 1.00
Level 3 THY Calibrator; mean	450 - 830
Level 3 THY Calibrator; SD	≤ 25

g. Review the MCAS mAU data:

In the mAU data you will see the cascade "Blank" cuvette that contains the Cascade reagents without chrome. The value represents the mAU rate from 42 to 300 seconds at 510 nm minus 700 nm.

1. From the Operating Menu, press **F5: Process Control**, then **F7: Method Review**.
2. Select the MCAS "method" using the **Alt / TIBC / TP** keys.
3. Press **F1: Set Period**. Enter **1** and press **Return**. This calls up the current day's results.
4. Press **F6: Next Fluid** until you get the **Urine QC1**.
5. Press F3 until "**See Histogram**" is displayed on the function key and the results are shown in a column.
6. Use **F2: Delete Results** to delete values from 1 – 6 from the Level 3 THY Calibrator results. Note: Only values 1-6 may be deleted. Specif. are based on an n=20 for Level 1.
7. Print the data (**F8**) and press **N** (you do not want a summary; you want all data).

Acceptable results for MCAS are listed below:

Test	Performance Limits (mAU)
MCAS: mean	1 - 60

8. Record the MCAS mean on the data sheet.

h. Review the CRQC mAU data. This function captures the chrome mAU data.

1. From the Operating Menu, press **F5: Process Control**, then **F7: Method Review**.
2. Select the CRQC "method" using the **Alt / PTN / NAK** keys.
3. Press **F1: Set Period**. Enter **1** and press **Enter.** This calls up the current day's results.
4. Press **F6: Next Fluid** until you get to **Urine QC2**.
5. Press F3 until "**See Histogram**" is displayed on the function key and the results are shown in a column.
6. Use **F2: Delete Results** to delete values 1 – 6 from the Level 3 THY Calibrator results.
   NOTE: Only values 1-6 may be deleted. Specif. are based on an n=20 for Level 1.
7. Print the data (F8) and press N (you do not want a summary; you want all data).

Acceptable results for CRQC are listed below:

Test Performance	Limits (mAU)
CRQC: mean	65 – 110
CRQC: SD	≤ 5.0

8. Record the CRQC mean and SD on the data sheet.

VISHWARAJ HOSPITAL
13:24 Jul 17 2019

SYSTEM CHECK

Entered: 13:19 Jul 17 2019

Status: PASS
CHK Flex Lot # GA2043
PHOTOMETER

Wavelength	Maximum
293nm	0.20
340nm	0.11
383nm	0.09
405nm	0.09
452nm	0.15
510nm	0.14
540nm	0.14
577nm	0.14
600nm	0.15
700nm	0.18

REAGENT #1		Results	
Mean:	397.10	1st	398.94
SD:	2.54	2nd	398.97
		3rd	398.56
		4th	395.80
		5th	393.22

REAGENT #2		Results	
Mean:	399.96	1st	399.27
SD:	0.48	2nd	400.07
		3rd	400.46
		4th	400.30
		5th	399.69

SAMPLER		Results	
Mean:	38.93	1st	38.19
SD:	0.41	2nd	39.04
		3rd	39.15
		4th	39.13
		5th	39.13

HM WASH	Results	
Mean:	1st	W1
SD:	2nd	W1
	3rd	W2
	4th	W2
	5th	W2

VISHWARAJ HOSPITAL
13:29 Jul 18 2019

SYSTEM CHECK

Entered: 13:24 Jul 18 2019

Status: PASS
CHK Flex Lot # GA2043
PHOTOMETER

Wavelength	Maximum
293nm	0.24
340nm	0.41
383nm	0.32
405nm	0.31
452nm	0.29
510nm	0.20
540nm	0.12
577nm	0.11
600nm	0.11
700nm	0.14

REAGENT #1		Results	
Mean:	398.00	1st	397.71
SD:	0.32	2nd	398.27
		3rd	398.19
		4th	398.22
		5th	397.60

REAGENT #2		Results	
Mean:	397.65	1st	396.51
SD:	1.10	2nd	399.35
		3rd	397.38
		4th	398.01
		5th	397.00

SAMPLER		Results	
Mean:	39.00	1st	39.04
SD:	0.13	2nd	39.18
		3rd	39.06
		4th	38.92
		5th	38.83

HM WASH	Results	
Mean:	1st	W1
SD:	2nd	W1
	3rd	W2
	4th	W2
	5th	W2

VISHWARAJ HOSPITAL
13:38 Jul 19 2019

SYSTEM CHECK

Entered: 13:33 Jul 19 2019

Status: PASS
CHK Flex Lot # GA2043
PHOTOMETER

Wavelength	Maximum
293nm	0.40
340nm	0.31
383nm	0.31
405nm	0.34
452nm	0.37
510nm	0.32
540nm	0.32
577nm	0.41
600nm	0.32
700nm	0.29

REAGENT #1
Mean: 398.12
SD: 1.06

Results
1st 397.37
2nd 397.89
3rd 396.97
4th 399.54
5th 398.85

REAGENT #2
Mean: 400.61
SD: 1.66

Results
1st 398.95
2nd 402.37
3rd 402.10
4th 400.75
5th 398.88

SAMPLER
Mean: 39.09
SD: 0.16

Results
1st 38.95
2nd 39.27
3rd 39.09
4th 39.24
5th 38.90

HM WASH
Mean:
SD:

Results
1st W1
2nd W1
3rd W2
4th W2
5th W2

Voltages:

Wall Receptacle	Power OFF	Power ON	Power ON
G-H	_____ V (0-1V)	_____ (90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
H-N	_____ V (0-1V)	_____ (90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
G-N	_____ V (0-1V)	_____ (Max 0.5)	_____ (< 2V)
	_____ V (0-1V)	_____ (< 2 V)	

Gaps:
Syringe

(Glass to plunger)	Observed	Adjusted	Specification
Sample Metering	OK	OK	(.005" - .010")
Sample Flush	OK	OK	(.005" - .010")
Reagent 1 Metering			(.005" - .010")
Reagent 1 Flush	OK	OK	(.005" - .010")
Reagent 2 Metering			(.005" - .010")
Reagent 2 Flush	OK	OK	(.005" - .010")
Reagent 3 Flush			(.005" - .010")
IF HM Instrument Chemistry Wash	OK	OK	(.005" - .010")
Cuvette Manufacture Solenoids			Specification
Top Seal	OK	OK	(.010" *)
Cuvette Form			(0.020" 0.045"**)
U-Seal			(0.020" = 0.010"*)
Capstan			(.005" = 0.010"*)

* Cuvette solenoid gaps are in the energized state with film installed.
** Solenoid gap is determined with solenoid de-energized and by manually pushing the solenoid shaft/armature forward until able to seal airflow with compressor and top seal (cuvette air valve) turned on.) The gap when solenoid is energized is likely to be zero.

NOTE: Any adjustments made must be recorded on the Installation Rating Form.

Installation Training/Operator Qualification

Topic: Brief Component Overview

Operators Key	Operators Other	Activity	Reference
☑	☑	Review system components	Operator's Guide, *System Overview*
☑	☐	Review keyboard, touchscreen and alert keys	Operator's Guide, *System Overview*
☑	☐	Review HM components	Operator's Guide, *System Overview*

Topic: Calibration

Operators Key	Operators Other	Activity		Reference
☑	☐	Calibrate linear methods	# methods:	Operator's Guide, *Calibration and Quality Control*
☑	☐	Calibrate logit methods	# methods:	Operator's Guide, *Calibration and Quality Control*
☑	☐	Verify enzyme methods	# methods:	Operator's Guide, *Calibration and Quality Control*
☑	☐	Calibrate Urine Drugs of Abuse methods	# methods:	Operator's Guide, *Calibration and Quality Control*

Topic: Maintenance **Do these procedures using the Maintenance Log**

Operators Key	Operators Other	Activity	Reference
☑	☐	Do daily maintenance procedures	Operator's Guide, *Setup and Supplies*
☑	☐	Do Weekly Maintenance procedures	Operator's Guide, *Maintenance*
☑	○	Do monthly maintenance procedures	Operator's Guide, *Maintenance*
☑	○	Review IMT tube routing	Operator's Guide, *Maintenance*
		Do these periodic maintenance procedures:	Operator's Guide, *Maintenance*
☑	○	Controlled power shutdown	Operator's Guide, *Maintenance*
☑	☐	Replace cuvette nozzle diaphragm	Operator's Guide, *Maintenance*
☑	☐	Replace printer paper	Operator's Guide, *Maintenance*
☑	☐	Replace cuvette film cartridge	Operator's Guide, *Maintenance*
☑	○	Replace probe tip	Operator's Guide, *Maintenance*
☑	○	Perform selected alignments	Operator's Guide, *Setup and Supplies*
☑	○	Review IMT pathway and IMT flow	Operator's Guide, *Maintenance*, *Troubleshooting*
☑	☐	Review replacing IMT consumables	Operator's Guide, *Setup and Supplies*
☑	☐	Review resolving a failed Dilcheck	Operator's Guide, *Setup and Supplies*
☑	☐	Review replacing HM consumables	Operator's Guide, *Setup and Supplies*

Topic: Sample Processing

Operators: Key	Operators: Other	Activity	Reference
☑	☐	Process patient sample using sample cup, primary tube (include barcoded tube if used)	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Process multiple fluid types, including urine assays	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Enter manual dilution factor	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Respond to system need: use ALT N to review needs screen	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Add and remove reagent cartridges	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Use ALT S to determine segment status and to delete segments	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Process short sample: • use ALT I. to respond to Insufficient Sample message • use SSC • use sample cup • use tube fill guide before processing	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Review use of sample status key, F2	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Edit samples, including adding and deleting tests, rerunning tests and deleting samples	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Use CTL Help and ALT R in response to reagent management icon	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Perform manual query, if used	Operator's Guide, *Sample Processing and Test Reports*
☑	☐	Review use of these keys: Pause — Exit/Shift Exit Reset — Backspace/Backslash Run — Up Arrow/Down Arrow Alarm — Pg Up/Pg Down CTL Stop	Operator's Guide, *System Overview*
☑	☐	Review Help functions/keys: Help, ALT Help, CTL Help, Shift Help	Operator's Guide, *Appendix*
☑	☐	Review these key combinations: ALT I, ALT P, ALT O	Operator's Guide, *Appendix*
☑	☐	Review interpreting test report messages	Operator's Guide, *Appendix*

Topic: Customization (continued)

Operators		Activity	Reference
Key	Other		
☑	○	Configuring QC Alerts	Operator's Guide,
☑	○	Defining QC Ranges	Operator's Guide
☑	○	Defining QC Products	Operator's Guide,
☑	○	Editing QC Products	Operator's Guide,
☑	○	Defining QC Panels	Operator's Guide,
☑	○	Defining Calibration Products	Operator's Guide,
☑	○	Configuring Calibration Alert	Operator's Guide
☑	○	Setting up Calibration Auto Acceptance	Operator's Guide,
☑	○	Grouping Calibration Alerts	Operator's Guide,
☑	○	Setting Up Calibrations Manually	Operator's Guide
☑	○	Grouping QC Alerts	Operator's Guide,
☑	○	Retrieving Calibration History	Operator's Guide,
☑	○	Storing Laboratory Data	Operator's Guide,

Topic: Problem Resolution

Operators		Activity	Reference
Key	Other		
☑	☐	Review response to alarm ON/OFF	Operator's Guide, *Introducing,*
☑	☐	Review response to error messages using ALT M	Operator's Guide, *Introducing*
☑	☐	Review using Reset key to clear error messages	Operator's Guide, *Introducing*
☑	○	Review active and resident error logs; including More Info and See Minor functions	Operator's Guide, *Troubleshooting*
☑	☐	Review troubleshooting, emphasizing system check troubleshooting guidelines	Operator's Guide, *Troubleshooting*
☑	○	Review icons and using CTL Help to respond to icons	Operator's Guide, *Appendix*

Topic: Resources

Operators		Activity
Key	Other	
☐	☐	Review TAC contact process
☐	○	Review XLINK capability
☐	○	Review Method Inserts
☐	○	Review Fast Facts

Other Training Items

Operators		Activity
Key	Other	
○	○	
○	○	
○	○	
○	○	

☐ - Required

○ - Optional

VISHWARAJ HOSPITAL

13:30 JUl 18 2019

REAGENT CARTRIDGE INVENTORY

METHOD	LOT NUMBER	SEQUENCE NO.	TESTS LEFT
ALB	FA2027	49998	56
ALPI	EB2069	37114	47
ALTI	FA2152	29309	39
AST	FA2088	09553	2
BUN	FB2007	46862	54
CHK	GA2043	29332	0
CHK	GA2043	29331	0
CRE2	GB2075	54160	0
CRE2	GB2075	54156	108
DBI	FB2144	47324	19
GLUC	GB1292	10012	185
TBI	GA2068	01874	42
TP	EA2042	10883	22
URCA	FA2018	46106	0
URCA	FA2018	46104	38

the end

13:39 Jul 19 2018

REAGENT CARTRIDGE INVENTORY

METHOD	LOT NUMBER	SEQUENCE NO.	TESTS LEFT
ALB	FA2027	49998	56
ALPI	EB2069	37114	47
ALTI	FA2152	29309	39
AST	FA2088	09553	2
BUN	FB2007	46862	54
CHK	GA2043	29332	0
CHK	GA2043	29326	5
CHK	GA2043	29331	0
CRE2	GB2075	54160	0
CRE2	GB2075	54156	108
DBI	FB2144	47324	19
GLUC	GB1282	10012	185
TBI	GA2068	01874	42
TP	EA2042	10883	22
URCA	FA2018	46106	0
URCA	FA2018	46104	38

the end

INVENTORY SUMMARY

ATTACH INVENTORY PRINTOUT

THIS INVENTORY SUMMARY CONSISTS OF ALL METHODS CALIBRATED AND INTENDED FOR USE AT TIME OF INSTALL.

CAS	CUSTOMER

CHEMISTRY INSTALLATION

1. CUSTOMIZING Dimension®EXL™

- ❑ 1.1 Review auto-dilution and automatic urine dilution feature with operator.
- ❑ 1.2 Add all auto-dilution parameters under each method.
- ❑ 1.3 Review auto repeat of panic values feature.
- ❑ 1.4 Review automatic reflex testing feature.
- ❑ 1.5 Insert panic values on the method parameters display.
- ❑ 1.6 Select operating mode for customer. Configure HIL Alert Index Values (auto-on ONLY).
- ❑ 1.7 Configure Alert key options.
  - a. STAT
  - b. Supplies – Reagent Alert Set-up ie. Gluc 50 – workload dependent
  - c. Calibration threshold – max 2140 hrs., recommend – 10-12 hrs.
- ❑ 1.8 Under System Configuration
  - Automatic dilution - YES
  - Auto repeat of Panics - Customer decision ON/OFF
  - Automatic Reflex Testing - Customer decision ON/OFF
  - Auto-Rerun - YES
  - Automatic Cartridge Removal: ON
- ❑ 1.9 ECO2 Configuration
  - TCO2 to ECO2 LIS info in computer ID
  - IMT Lytes key to include ECO2, set soak interval, more than 100 lytes a day, 15 day interval
  - Test Report Order: to move ECO2 with LYTES

QCC PowerPak CAS Installation

1. Instrument Setup

1.1. Configure QC Alerts

Provides a means to setup new QC Alerts.

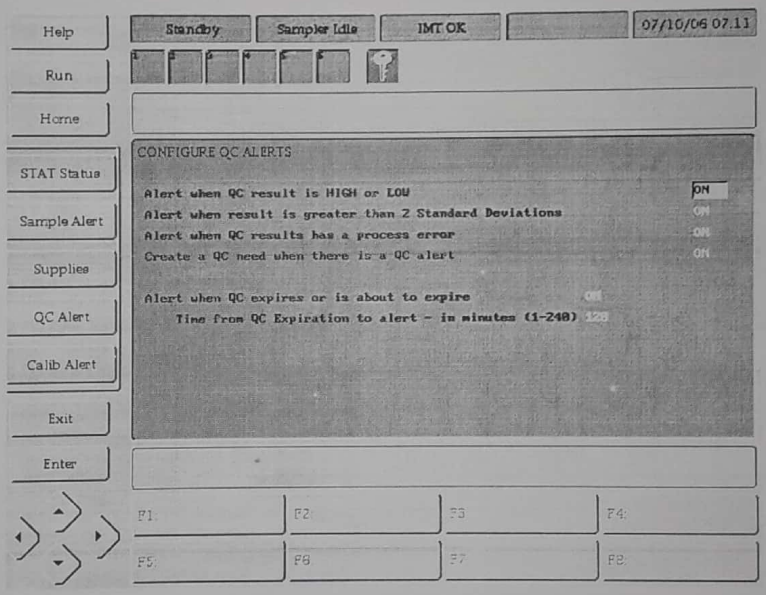
- Enter into the Screen by pressing the following:
  Select QC Alert
  F4: Configure Alert

Turn on requested alerts for the following:

Alert when QC result is High or Low
Alert when result is greater than 2 SD
Alert when QC results has a process error
Create a QC need when there is a QC Alert

- Set time for QC Expiration to alert as preferred

Note: If the "Create a QC need when there is a QC Alert" is enabled the user will not get the timed QC Alert.

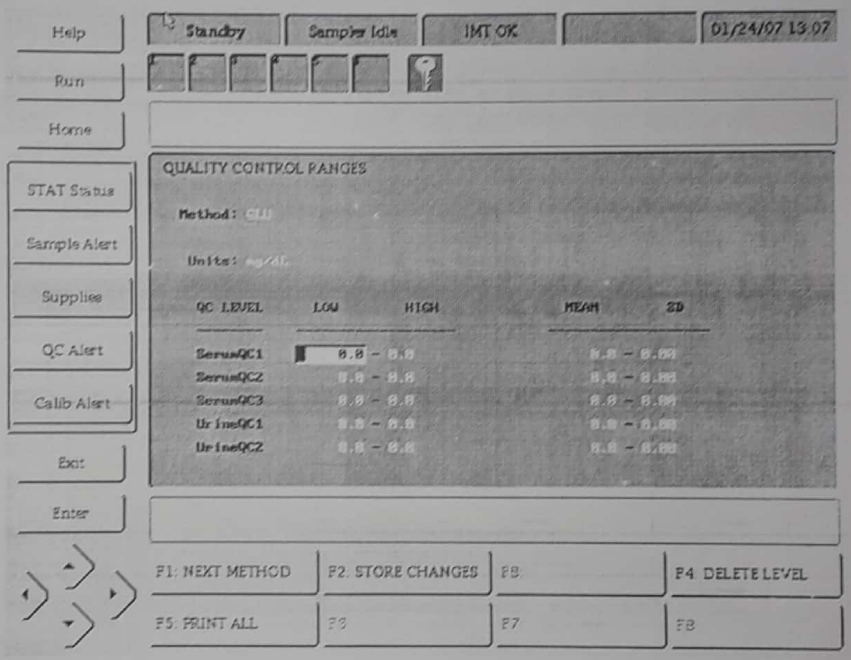


1.2. Define QC Ranges

Uses current functionality to Define QC Ranges which will be used by the QC Program as well as the Calibration program.

- Enter into the Screen from the Main Menu
  - F5: Process Control
  - F4: QC Ranges
- Select Method
  - Enter QC Ranges for method
  - F2: Store Changes
- Repeat procedure for all methods

Note: Each analyte needs a minimum of (2) QC ranges set.

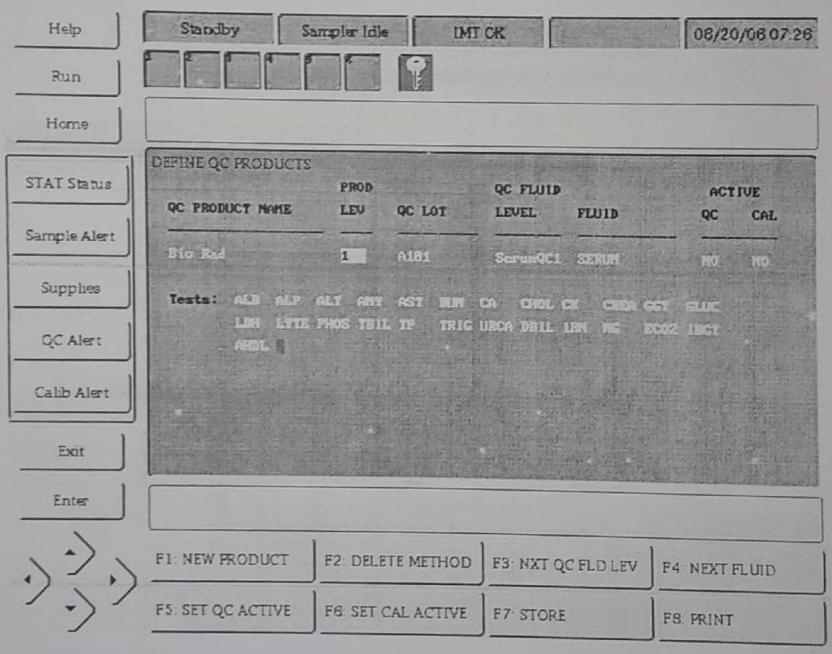


1.3. Defining QC Products

Entering QC Products allows specific QC products to be associated with product levels, methods, QC fluid levels (SerumQC1, UrineQC1…) and fluids (SERUM, URINE, CSF/WHOLE BLOOD…). These definitions are used to define what QC products are to be run with a calibration (provides a picks list when the calibration is setup), what fluid is sent to the LIS, and where the QC should be sent to in the Dimension® QC database.

- Enter into the Screen by pressing the alert button
  - Select QC Alert
  - F5: Define QC Product
- Input QC Product information including QC Product Name, Product Level, QC Lot number, QC Fluid Level, Fluid Type. Select Tests and set the QC and Calibration Active
  - F7: Store
- Change Product Level and QC Fluid Level (if additional levels and fluids are needed for this product)
  - F7: Store
- Repeat for each QC Product

Note: The user should define all levels for a product before setting up additional products.



Edit QC Products

- Enter into the Screen from the main menu by selecting:
  - F5: Process Ctrl
  - F3: QC Status
  - F2: Edt QC Product
  - Select the QC Product to be edited
  - F1: Edit Product

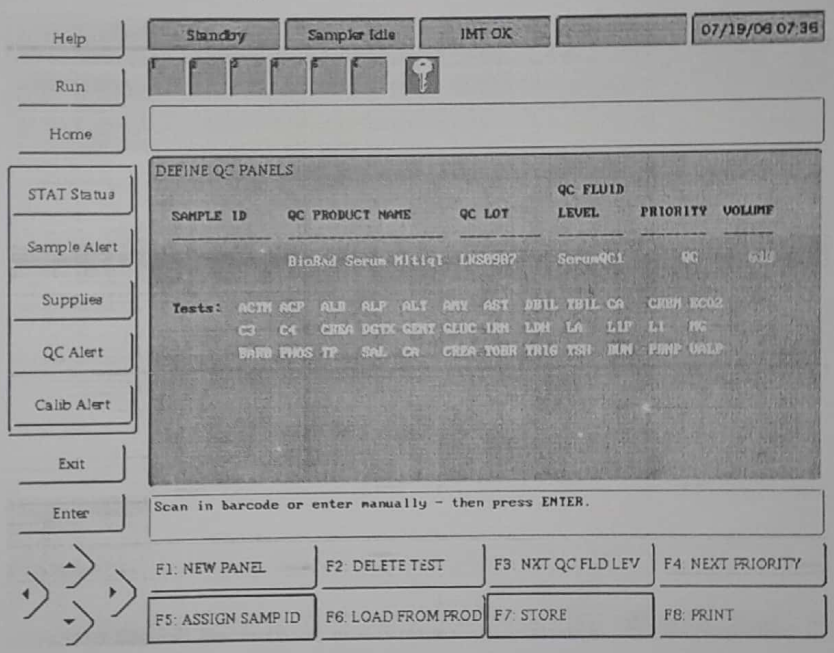
Make changes to the product using function keys

1.4. Defining QC Panels

This feature is intended to provide the means to match a Barcode ID to a panel of methods on which QC is required on a periodic basis.

- Enter into the Screen from the Main Menu
  - F5: Process Control
  - F3: QC Status
  - F6: Define QC Panels
  - F6: Load from Prod
- Cursor down to the product to set up a QC Panel
  - F1: Select Product
    - F5: Assign Sample ID (scan in or manually enter the sample ID for the QC)
  - F7: Store
- Repeat process to set up all QC Panels

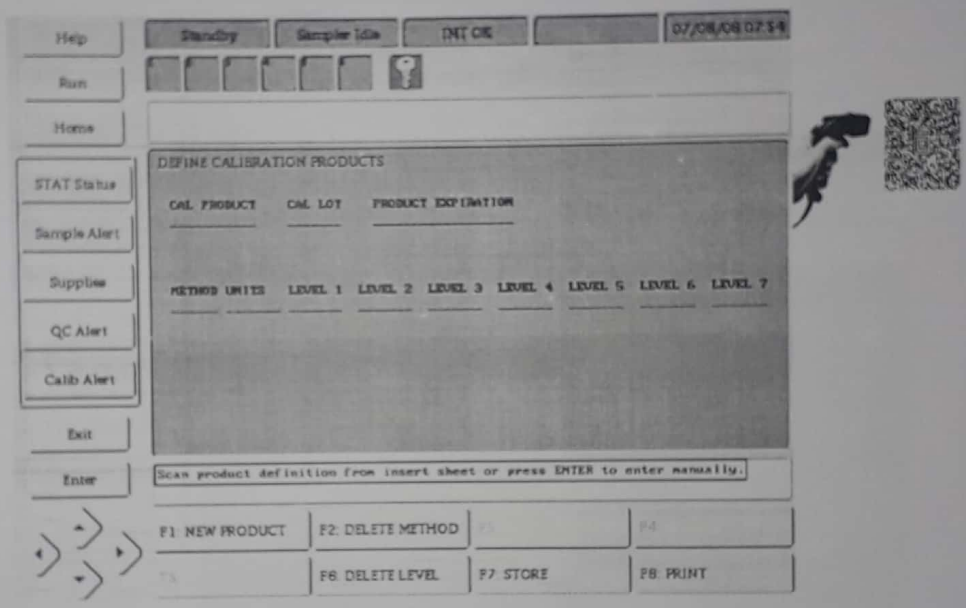
Note: When scanning in barcodes make sure that the caps lock function is turned off.



1.5. Define Calibration Products

Provides a means to scan or manually enter calibration product definitions that include the product name, lot number, expiration date and bottle values for each method in the product. Bottle values for the product are in U.S. and S.I. units.

- Enter into the Screen by:
  - Select Calibration Alert
  - F5: Define Cal Product
- Scan in Product with barcode reader
  - F7: Store
- Repeat



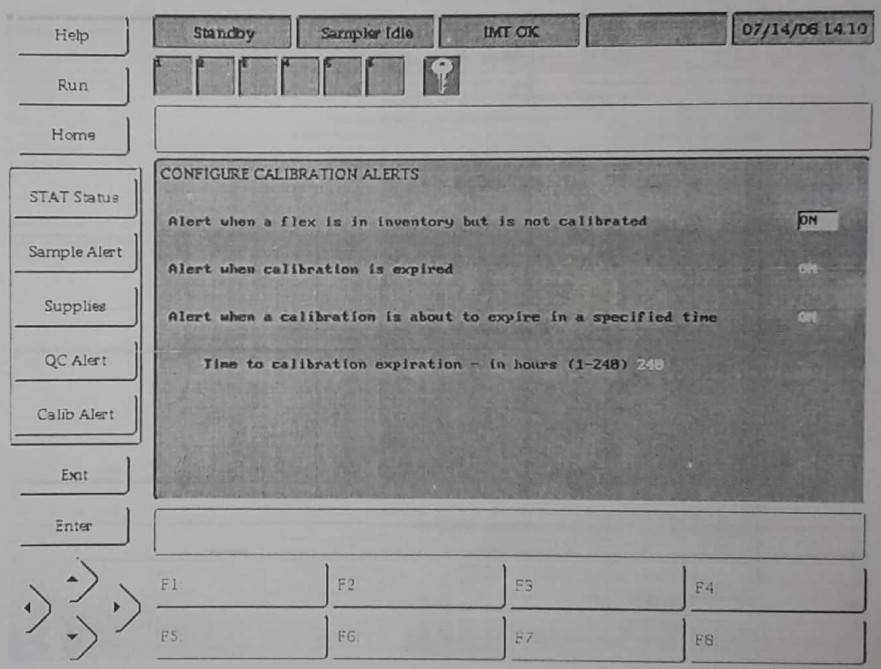
1.6. Set Calibration Alerts

Provides a means to alert customer when a calibration is needed, or about to be needed on the system.

- Enter into the Screen by:
  Select Calib Alert
  F4: Config Alert
- Turn on requested alerts for:

Flex in inventory but not calibrated
Alert when expired
Alert when about to expires
Program time to calibration expiration

- Exit out of the screen (values will store upon exit)

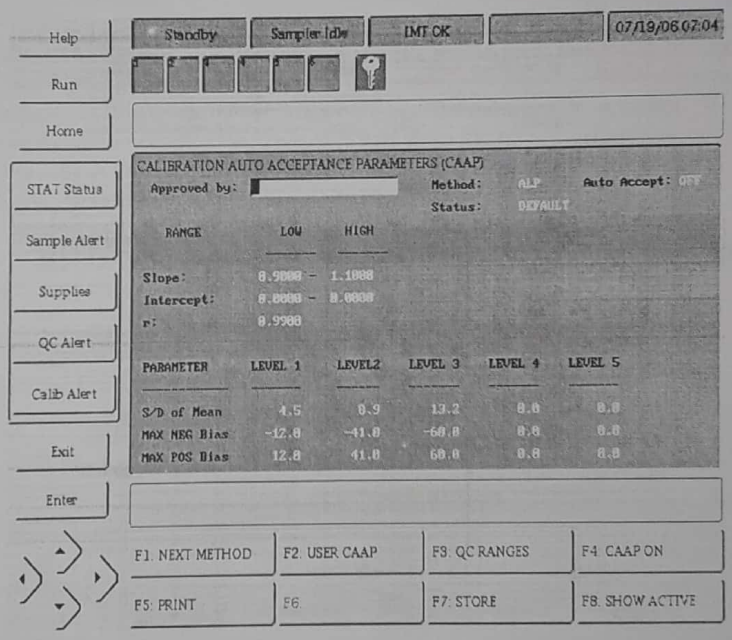


1.7. Setup Calibration Auto-Acceptance

The auto-accept screen requires that each method be individually selected, the parameters reviewed, the approvers name entered, then enabling auto-accept.

- Enter into the Screen from the main operating menu select:
  - F5: Process Control
  - F1: Calibration
- Enter Password
  - F4: Auto-Accept
- Select Method
- Review the information on the screen, modify any information necessary
- Enter name in the Approved by: space
  - F4: CAAP On (for methods that customer wants Auto Accepted)
  - F7: Store

Note: CAAP stands for Calibration Auto Acceptance Parameters



1.8. Load Reagent Flexes

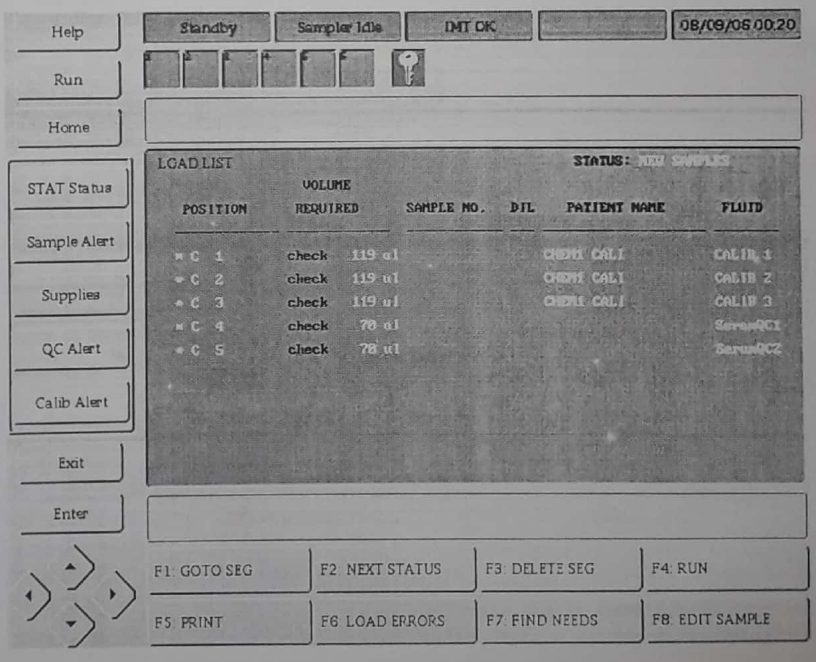
Add any reagent flexes to the instrument needed. If possible add new lots of reagents or reagents that need calibrated so that the customer can get familiar with the Calibration Auto Acceptance.

2. Calibration

2.1. Calibration Setup (Automatic Acceptance)

- Select Calib Alert
  F3: Group Cals
- Select product/methods to be calibrated
  F2: Setup Group
  Note: if more then one calibrator product is defined for that group, the product that matches the calibrator lot number must be selected.
- Enter users initials
- Enter starting cup position
  F4: Assign cups
  F7: Load/Run
  F4: Run

When the calibration is complete a report slip will print indicating the acceptance status from the auto-accept routine. If the calibration was auto-accepted, the report slip would indicate so and no further action would be required from the operator. If calibration was not auto-accepted, the customer will go to the review calibration screen and manually review the calibration.
Note: Information displayed will be the calculated information.



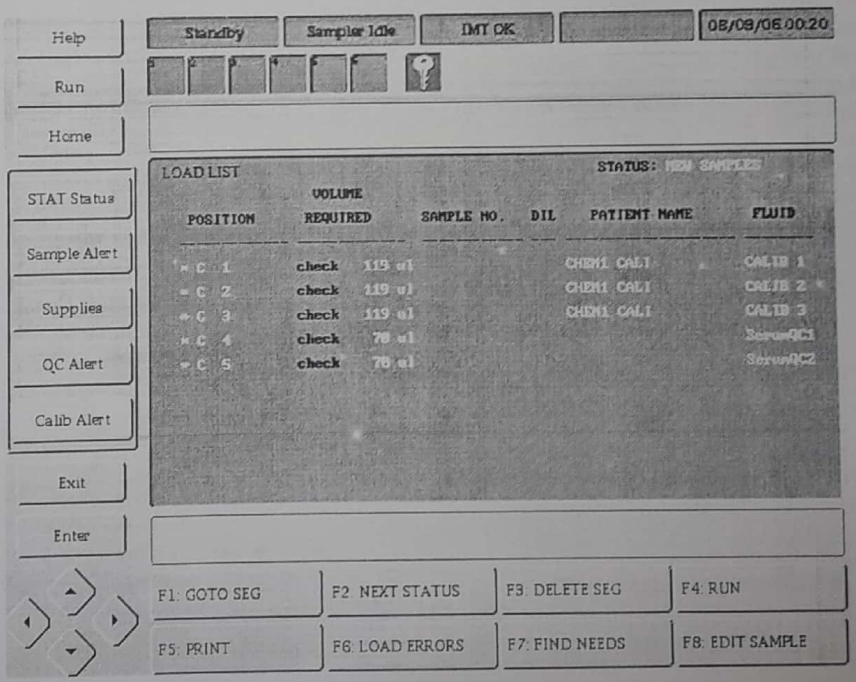
2.2 Calibration Setup (Manual)

Enter a calibration the normal way.

- From the Main Menu select:
  - F5: Process Ctrl
  - F1: Calibration
- Enter password
  - F2: Set-Up Run
- Select method to be calibrated
  - Note: if more then one calibrator product is defined for the method then the product that matches the calibrator lot number must be selected.
- Enter Operators Name
- Select Start Position
  - F8: QC Yes/No
  - F4: Assign Cups
  - F7: Load/Run
  - F4: Run

Allow the calibration to run, when the calibration is complete a report slip will print indicating the acceptance status from the auto-accept routine. If the calibration was auto-accepted, the report slip would indicate so and no further action would be required from the operator. If calibration was not auto-accepted, the customer will go to the review calibration screen and manually review the calibration.

Note: Information displayed will be the calculated information.

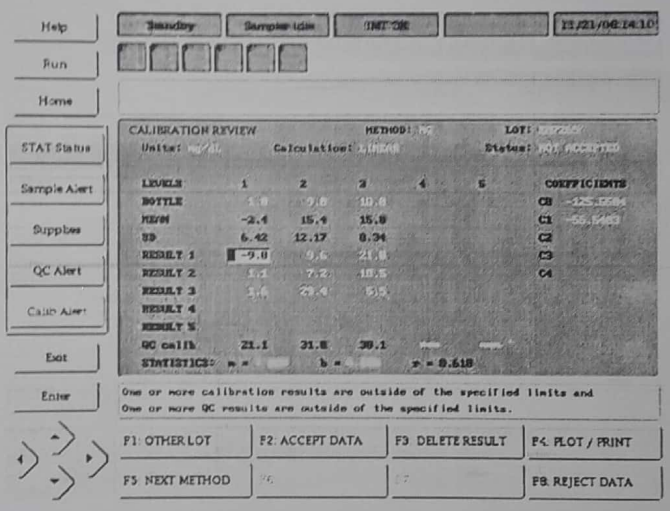


2.3 Calibration Review

Calibration Review has been modified for auto-acceptance methods to display errant values that are outside of the expected slope, intercept, mean s.d. and QC in RED and values in range in GREEN.

- From the Main Menu select:
  - F5: Process Ctrl
  - F1: Calibration
- Enter Password
  - F3: Review Data
- Select Method to be reviewed:

Note: Only look at methods that have been calibrated since QCC PowerPak has been turned on.

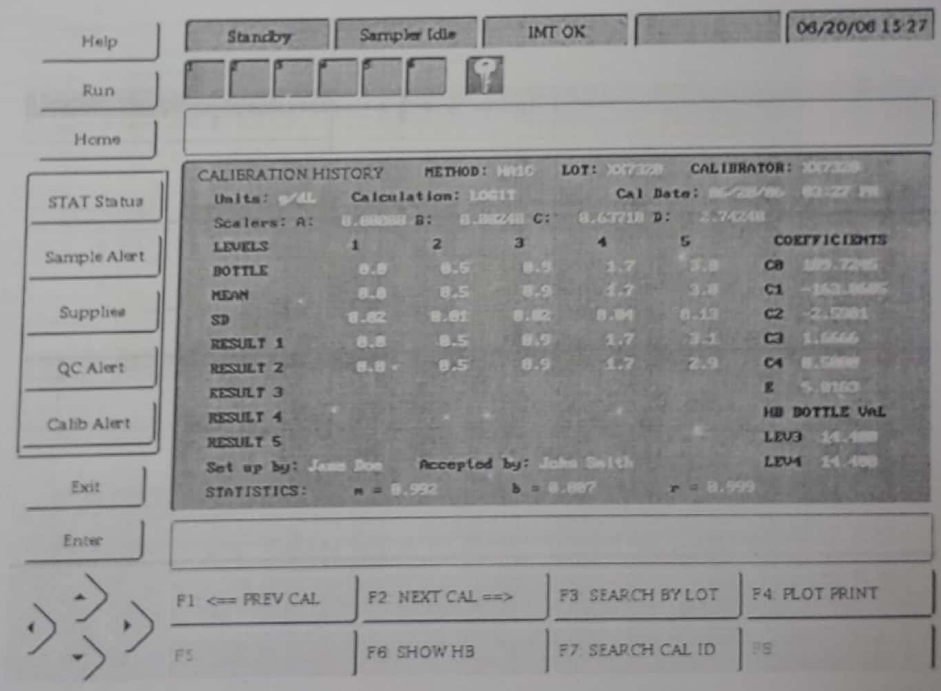


- Items that passed are in green and those that failed are in red
- Displayed shows that the mean, SD, QC and correlation coefficient is outside of acceptable range.
- After review, information can be manually accepted, if desired, using the F2: ACCEPT DATA function

2.4 Calibration History

Calibration History provides the user with the ability to review and print calibrations that have previously been completed, system starts archiving calibration history for any method that has been calibrated once QCC PowerPak is enabled.

- From the main menu
  - F5: Process Ctrl
  - F1: Calibration
- Enter Password
  - F7: Calib History
- Select Method to review
- Select the desired calibration by selecting:
  - F1: Prev Cal
  - F2: Next Cal
  - F3: Search by Lot
  - F4: Search by Cal ID
- Select Plot / Print
  - F4: Plot Print (if desired)
- When asked "Do you want to print a report?" answer Y



2.5 Store Laboratory Data

Improvements to the STORE LABORATORY DATA feature include adding calibrations records and enabling writing the data to a memory stick though the USB port.

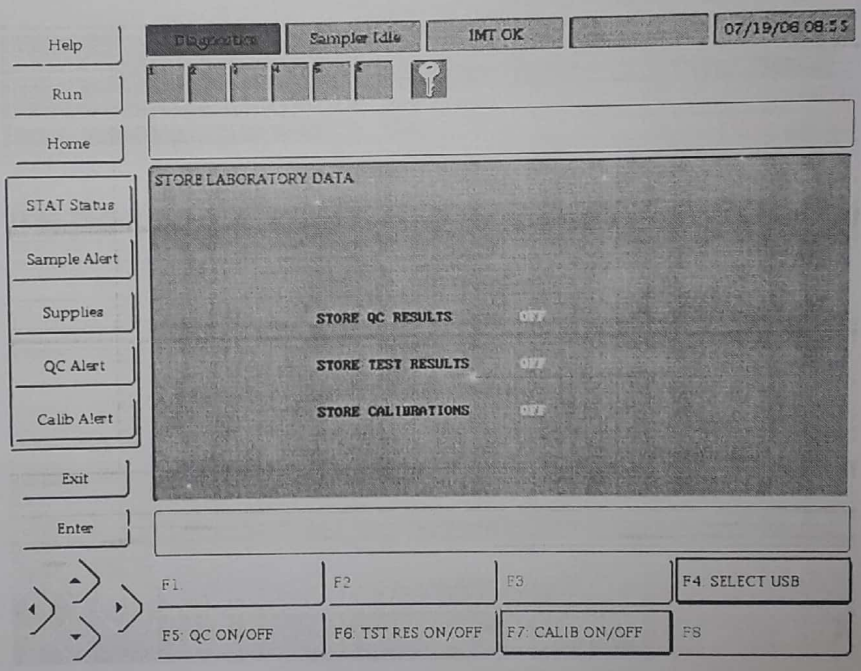
- From the Main Menu select:
  - F5: Process Ctrl
  - F8: More Options
  - F7: Store Lab Data

Use the F4: function key to toggle the storage device (either Floppy or USB)

- Select the date range to store data
  - F1: Store Data

Follow prompts on screen to store data

Note: Instrument should be in standby when storing laboratory data.



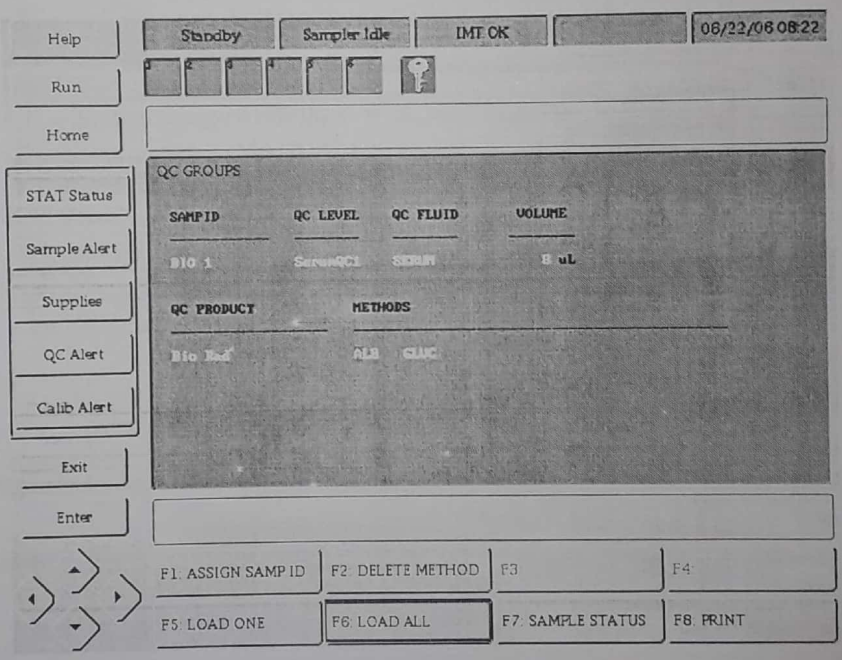
3. QC

3.1. Group QC Alerts

The Group QC Alert function allows grouping of QC alerts to common QC Products. This allows errant QC mitigation by assigning a sample ID to a dynamic QC panel based on QC needs.

- Select QC Alert
  F6: Group Alerts
- Select the QC product that you wish to run from the list
  F1: Assign Samp ID
- Enter the sample ID
  F5: Load One (if multiple alerts are available, assign the first sample ID then cursor down and assign the next ID until all samples have ID's, the user then can select F5: Load All.

Note: If this is a rerun of the QC the sample will need to be moved to a new location.



QCC PowerPak™ Installation Checklist

Configure QC Alerts	
Define QC Ranges	
Define QC Products	
Define QC Panels	
Define Calibration Products	
Set Calibration Alerts	
Setup Calibration AUTO-ACCEPTANCE	
Load Reagent Flexes	

Calibration Setup (AUTOMATIC ACCEPTANCE)	
Calibration Setup (MANUAL)	
Calibration Review	
Calibration History	
Store Laboratory Data	

Group QC Alerts	

Clinical Applications Specialist: _____

Install date: _____

CALIBRATION/VERIFICATION PRODUCT LOT NUMBERS

Serial Number:_____

IMT REAGENTS/SUPPLIES

_____ QuikLYTE® Cartridge
_____ Salt Bridge Solution
_____ QuikLYTE® Standard A
_____ QuikLYTE® Standard B
_____ Dilution Check
_____ QuikLYTE® Sample Diluent

HM REAGENTS/SUPPLIES

_____ Reaction Vessels
_____ Chemistry Wash
_____ Reagent Probe Cleaner
_____ HM IMT Probe Cleaner
_____ Sample Probe Cleaner
_____ HM Sample Diluent

CALIBRATION DATA

METHOD _____ FLEX LOT #_____ CALIB LOT #_____

SD = _____ at _____ SD = _____ at _____ SERIAL #_____

SLOPE GUIDELINE_____ SUGGESTED INTERCEPT_____

C0 = _____ C1 = _____

ATTACH REPORT SLIP(S) IN THIS AREA

VISHWARAJ HOSPITAL
14:33 Jul 19 2019

CALIBRATION

METHOD: GLUC LOT ID: GB1292

Entered: 14:22 Jul 19 2019
Operator: KIRAN
Calibrator Name: CHEM 1 CAL
Calibrator Lot: OLD077
Calibration status: NOT ACCEPTED

Calibration Curve: LINEAR
Units: mg/dL

C0: -0.976 C1: 0.916

BOTTLE	RESULT	ERROR
0	0	assay range
0	0	assay range
0	0	assay range
274	275	
274	273	
274	273	
538	546	assay range
538	545	assay range
538	539	assay range

QC RANGE	RESULT	ERROR
73-97		
247-297		
*** - ***		
0-0		
0-0		
0-0		
0-0		
0-0		
0-0		
0-0		

VISHWARAJ HOSPITAL
14:36 Jul 19 2019

CALIBRATION REVIEW
Instrument Serial Number: 271193

METHOD: GLUC LOT: GB1292
CALIB. PRODUCT/LOT: CHEM 1 CAL - OLD077

Status: CALIBRATED
Set up by: KIRAN
Set up date: 07/19/19 02:22 PM
Accepted by: KIRAN
Acceptance date: 07/19/19 02:36 PM
Acceptance mode: MANUAL
CAAP status:

Cal ID: 1907191436.GLUC.GB1292

Units: mg/dL
Calculation: LINEAR

Calibration Coefficients
C0: 0.2645
C1: 0.9066
C2:
C3:
C4:

LEVEL	1	2	3	4	5
BTTL	0	274	538	***	***
MEAN	0.9	272.2	538.9	***	***
SD	0.1	0.9	4.1	***	***
#1	1	273	542	***	***
#2	1	272	540	***	***
#3	1	272	534	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics
m = 1.000
b = 0.000
r = 1.000

QC LEVEL	REF. INTERVAL	RESULT
#1	72.94-97.06	***
#2	248.7-297.2	***
#3	*** - ***	***
#4	0.000-0.000	***
#5	0.000-0.000	***

VISHWARAJ HOSPITAL
14:33 Jul 19 2019

CALIBRATION

METHOD: CRE2 LOT ID: GB2075

Entered: 14:21 Jul 19 2019
Operator: KIRAN
Calibrator Name: CHEM 1 CAL
Calibrator Lot: OLD077
Calibration status: NOT ACCEPTED

Calibration Curve: LINEAR
Units: mg/dL

C0: -0.423 C1: 0.077

Scalers: A: 0.000000 B: 0.000000
C: 1.000000 D: -0.050000

BOTTLE	RESULT	ERROR
0.00	-0.08	assay range
0.00	-0.05	assay range
0.00	-0.06	assay range
10.97	10.48	
10.97	10.54	
10.97	10.77	
21.61	21.48	assay range
21.61	21.39	assay range
21.61	21.14	assay range

QC RANGE	RESULT	ERROR
2.18-3.03		
5.25-6.74		
*** - ***		
0.00-0.00		
0.00-0.00		
0.00-0.00		
0.00-0.00		
0.00-0.00		
0.00-0.00		
0.00-0.00		

VISHWARAJ HOSPITAL
14:36 Jul 19 2019

CALIBRATION REVIEW
Instrument Serial Number: 271193

METHOD: CRE2 LOT: GB2075
CALIB. PRODUCT/LOT: CHEM 1 CAL - OLD077

Status: CALIBRATED
Set up by: KIRAN
Set up date: 07/19/19 02:21 PM
Accepted by: KIRAN
Acceptance date: 07/19/19 02:36 PM
Acceptance mode: MANUAL
CAAP status:

Cal ID: 1907191436.CRE2.GB2075

Units: mg/dL
Calculation: LINEAR

Calibration Coefficients
C0: -0.3650
C1: 0.0779
C2:
C3:
C4:

Scalers: A: 0.000000 B: 0.000000
C: 1.000000 D: -0.050000

LEVEL	1	2	3	4	5
BTTL	0.00	10.97	21.61	***	***
MEAN	0.000	10.803	21.693	***	***
SD	0.013	0.153	0.181	***	***
#1	-0.01	10.69	21.84	***	***
#2	0.01	10.75	21.74	***	***
#3	0.00	10.98	21.49	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics
m = 1.004
b = -0.069
r = 1.000

QC LEVEL	REF. INTERVAL	RESULT
#1	2.180-3.030	***
#2	5.250-6.740	***
#3	*** - ***	***
#4	0.000-0.000	***
#5	0.000-0.000	***

the end

VISHWARAJ HOSPITAL
14:35 Jul 19 2018

CALIBRATION

METHOD: AST LOT ID: GA2098

Entered: 14:19 Jul 19 2018
Operator: KIRAN
Calibrator Name: ENZ VERIFI
Calibrator Lot: 0GJ061
Calibration status: NOT ACCEPTED

Calibration Curve: VERIFY
Units: U/L

C0: 2.000 C1: -3.537

BOTTLE	RESULT	ERROR
36	38	
36	35	
36	36	
411	431	
411	437	
411	432	
785	816	
785	823	
785	824	

QC RANGE	RESULT	ERROR
35-51		
187-238		
*** - ***		
0-0		
0-0		
0-0		
0-0		
0-0		
0-0		
0-0		

VISHWARAJ HOSPITAL
14:35 Jul 19 2018

CALIBRATION REVIEW
Instrument Serial Number: 271193

METHOD: AST LOT: GA2098
CALIB. PRODUCT/LOT: ENZ VERIFI - 0GJ061

Status: CALIBRATED
Set up by: KIRAN
Set up date: 07/19/19 02:19 PM
Accepted by: KIRAN
Acceptance date: 07/19/19 02:35 PM
Acceptance mode: MANUAL
CAAP status:

Cal ID: 1907181435.AST.GA2098

Units: U/L
Calculation: VERIFY

Calibration Coefficients
C0: 2.0000
C1: -3.5370
C2:
C3:
C4:

LEVEL	1	2	3	4	5
BTTL	36	411	785	***	***
MEAN	36.2	433.1	820.9	***	***
SD	1.6	3.1	4.2	***	***
#1	38	431	816	***	***
#2	35	437	823	***	***
#3	36	432	824	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics

m = 1.048
b = -0.188
r = 1.000

QC LEVEL	REF. INTERVAL	RESULT
#1	34.80-51.10	***
#2	187.0-238.0	***
#3	*** - ***	***
#4	0.000-0.000	***
#5	0.000-0.000	***

VISHWARAJ HOSPITAL
14:36 Jul 19 2019

CALIBRATION

METHOD: ALB LOT ID: FA2027

Entered: 14:29 Jul 19 2019
Operator: KIRAN
Calibrator Name: TP/ALB CAL
Calibrator Lot: 0DD036
Calibration status: NOT ACCEPTED

Calibration Curve: LINEAR
Units: g/dL

C0: -1.06D C1: 0.023

BOTTLE	RESULT	ERROR
0.40	1.33	
0.40	1.34	
0.40	1.35	
4.10	5.49	
4.10	5.52	
4.10	5.53	
8.10	9.88	assay range
8.10	9.85	assay range
8.10	9.89	assay range

QC RANGE	RESULT	ERROR
3.69-4.37		
2.28-2.74		
*** - ***		
0.00-0.00		
0.00-0.00		
0.00-0.00		
0.00-0.00		
0.00-0.00		
0.00-0.00		
0.00-0.00		

VISHWARAJ HOSPITAL
14:43 Jul 19 2019

CALIBRATION REVIEW
Instrument Serial Number: 271193

METHOD: ALB LOT: FA2027
CALIB. PRODUCT/LOT: TP/ALB CAL - 0DD036

Status: CALIBRATED
Set up by: KIRAN
Set up date: 07/19/19 02:29 PM
Accepted by: KIRAN
Acceptance date: 07/19/19 02:43 PM
Acceptance mode: MANUAL
CAAP status:

Cal ID: 1907191443.ALB.FA2027

Units: g/dL
Calculation: LINEAR

Calibration Coefficients
C0: -1.7864
C1: 0.0207
C2:
C3:
C4:

LEVEL	1	2	3	4	5
BTTL	0.40	4.10	8.10	***	***
MEAN	0.377	4.144	8.079	***	***
SD	0.008	0.020	0.016	***	***
#1	0.37	4.12	8.09	***	***
#2	0.37	4.15	8.06	***	***
#3	0.39	4.16	8.09	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics
m = 1.000
b = 0.000
r = 1.000

QC LEVEL	REF. INTERVAL	RESULT
#1	3.690-4.370	***
#2	2.280-2.740	***
#3	*** - ***	***
#4	0.000-0.000	***
#5	0.000-0.000	***

VISHWARAJ HOSPITAL
14:58 JUL 19 2019

CALIBRATION

METHOD: TP LOT ID: EA2042

Entered: 14:45 Jul 19 2019
Operator: KIRAN
Calibrator Name: TP/ALB CAL
Calibrator Lot: ODD036
Calibration status: NOT ACCEPTED

Calibration Curve: LINEAR
Units: g/dL

C0: 3.700 C1: 0.022

BOTTLE	RESULT	ERROR
0.9	1.0	assay range
0.9	1.1	assay range
0.9	1.0	assay range
7.5	7.3	
7.5	7.2	
7.5	7.2	
14.8	13.6	assay range
14.8	13.5	assay range
14.8	13.6	assay range

QC RANGE	RESULT	ERROR
6.6-7.7		
4.1-4.9		
*** - ***		
0.0-0.0		
0.0-0.0		
0.0-0.0		
0.0-0.0		
0.0-0.0		
0.0-0.0		
0.0-0.0		

CALIBRATION REVIEW
Instrument Serial Number: 271193

METHOD: TP LOT: EA2042
CALIB. PRODUCT/LOT: TP/ALB CAL - ODD036

Status: CALIBRATED
Set up by: KIRAN
Set up date: 07/19/19 02:45 PM
Accepted by: KIRAN
Acceptance date: 07/19/19 02:58 PM
Acceptance mode: MANUAL
CAAP status:

Cal ID: 190719145B.TP.EA2042

Units: g/dL
Calculation: LINEAR

Calibration Coefficients
C0: 3.7566
C1: 0.0245
C2:
C3:
C4:

LEVEL	1	2	3	4	5
BTTL	0.9	7.5	14.8	***	***
MEAN	0.81	7.67	14.72	***	***
SD	0.01	0.04	0.01	***	***
#1	0.8	7.7	14.7	***	***
#2	0.8	7.7	14.7	***	***
#3	0.8	7.6	14.7	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics
m = 1.000
b = 0.000
r = 1.000

QC LEVEL	REF. INTERVAL	RESULT
#1	6.570-7.700	***
#2	4.100-4.910	***
#3	*** - ***	***
#4	0.000-0.000	***
#5	0.000-0.000	***

the end

VISHWARAJ HOSPITAL
14:29 Jul 19 2019

CALIBRATION

METHOD: TBI LOT ID: GA2068

Entered: 14:12 Jul 19 2019
Operator: KIRAN
Calibrator Name: TBI/DBI CA
Calibrator Lot: 0GD046
Calibration status: NOT ACCEPTED

Calibration Curve: LINEAR
Units: mg/dL

C0: 0.000 C1: 0.078

BOTTLE	RESULT	ERROR
0.0	0.1	assay range
0.0	0.1	assay range
0.0	0.1	assay range
9.8	9.9	
9.8	9.8	
9.8	9.9	
27.3	27.4	assay range
27.3	27.4	assay range
27.3	27.6	assay range

QC RANGE	RESULT	ERROR
0.6-1.1		
3.5-4.4		
*** - ***		
0.0-0.0		
0.0-0.0		
0.0-0.0		
0.0-0.0		
0.0-0.0		
0.0-0.0		
0.0-0.0		

VISHWARAJ HOSPITAL
14:23 Jul 19 2019

CALIBRATION REVIEW
Instrument Serial Number: 271103

METHOD: TBI LOT: GA2068
CALIB. PRODUCT/LOT: TBI/DBI CA - 0GD046

Status: CALIBRATED
Set up by: KIRAN
Set up date: 07/19/19 02:12 PM
Accepted by: KIRAN
Acceptance date: 07/19/19 02:23 PM
Acceptance mode: MANUAL
CAAP status:

Cal ID: 1907191423.TBI.GA2068

Units: mg/dL
Calculation: LINEAR

Calibration Coefficients
C0: -0.0763
C1: 0.0777
C2:
C3:
C4:

LEVEL	1	2	3	4	5
BTTL	0.0	9.8	27.3	***	***
MEAN	0.00	9.77	27.31	***	***
SD	0.01	0.02	0.08	***	***
#1	0.0	9.8	27.3	***	***
#2	0.0	9.8	27.3	***	***
#3	0.0	9.8	27.4	***	***
#4	***	***	***	***	***
#5	***	***	***	***	***

Statistics
m = 1.001
b = -0.013
r = 1.000

QC LEVEL	REF. INTERVAL	RESULT
#1	0.650-1.060	***
#2	3.530-4.420	***
#3	*** - ***	***
#4	0.000-0.000	***
#5	0.000-0.000	***

QUALITY CONTROL SUMMARY

ATTACH QC PRINTOUT

Attachment

VISHWARAJ HOSPITAL
15:18 Jul 19 2019

PRINT RESULTS

Patient: BIORAD L1
Sample No.:
Location:
Sample: SerumQC
Priority: QC
Entered: 15:02 Jul 19 2019

Position: 1
Segment: 8

TEST	RESULT	REF. INTERVAL	UNITS
TBI	0.9	0.8-1.1	mg/dL
TP	8.0	7.7-8.8	g/dL
ALB	4.18	3.69-4.37	g/dL
GLUC	80	73-97	mg/dL
DBI	0.2	0.1-0.3	mg/dL
CRE2	2.70	2.18-3.03	mg/dL

VISHWARAJ HOSPITAL
15:13 Jul 19 2019

PRINT RESULTS

Patient: BIORAD L2
Sample No.:
Location:
Sample: Seru-QC2
Priority: QC
Entered: 15:03 Jul 19 2019

Position: 2
Segment: 8

TEST	RESULT	REF. INTERVAL	UNITS
TBI	4.1	3.5-4.4	mg/dL
DBI	0.8	0.7-1.1	mg/dL
TP	5.5	5.1-6.9	g/dL
ALB	2.81	2.28-2.74	g/dL
CRE2	5.18 LO	5.25-6.74	mg/dL
GLUC	262	247-297	mg/dL
CRE2	6.02	5.25-6.74	mg/dL

CRE2 mean:5.60 sd:0.587 cv:10.67

COMPARATIVE STUDY

SPLIT SAMPLE COMPARISON*

DATE_____

X (CONFIRMED INSTRUMENT): _____ Y (NEW INSTRUMENT): _____

SERIAL#: SERIAL#:

	Method _____ Lot # _____		Method _____ Lot # _____		Method _____ Lot # _____		Method _____ Lot # _____		Method _____ Lot # _____	
Sample	x	y	x	y	x	y	x	y	x	y
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
	m = _____ b = _____ r = _____		m = _____ b = _____ r = _____		m = _____ b = _____ r = _____		m = _____ b = _____ r = _____		m = _____ b = _____ r = _____	

*NOTE: This is an alternate document to accommodate more than one method and for mailing of data

COMPARATIVE STUDY

SPLIT SAMPLE
HELPFUL HINTS

1. Samples to use

20 samples across assay range

- should be fresh if possible or preserved in appropriate manner
- 20% of samples should be at medical decision level
- 20% of samples should be at upper level of assay range
- should have adequate sample volume for running on both instruments
- samples, which are hemolyzed, icteric, etc. can be included if they are known not to interfere

2. Measurements

a. Run samples on calibrated and within current QC'd instruments. Check logs if necessary.

b. Specimens should be analyzed on the two instruments at the same time.

c. Ensure that both instruments are performing well

d. Have maintenance on both instruments up-to-date

e. Recalibrate both instruments, if necessary

f. Verify QC is within acceptable range

3. Data Review

a. Evaluate slope (m) and y-intercept (b). If acceptable, validation is complete

b. If the slope and intercept are not acceptable, the reason may be due to the range of samples that were tested. You should consider evaluating the bias at appropriate medical decision levels and compare to your requirement.

c. If methodologies are not similar (i.e., THYoids), evaluate data in terms of respective reference interval and whether normal or abnormal.

REFERENCE RANGE STUDY

INSTRUMENT SERIAL #_____ DATE_____

METHOD_____ FLEX LOT #_____

Samples used:_____
(lot #if applicable)

1. Statistics from split sample comparison:
   - Slope (m) =
   - y-Intercept (b) =
   - Correlation Coefficient (r) =
   - Bias =

OR

2. Calculation of Reference Interval from regression equation

OR

3. Statistics from 20 "normal, healthy" samples:
   - X of instrument being validated _____
   - X of comparative instrument _____
   - N _____
   - Simple Bias _____
   - SD of Bias _____
   - t-value _____

Conclusion:

Dade Behring Inc. Suggested Reference Interval _____

Laboratory Reference Interval _____

Validator _____ Date _____

Supervisor _____ Date _____

REFERENCE RANGE STUDY
HELPFUL HINTS

1. Samples to use

a. Normal and healthy patient samples

OR

b. Proficiency Testing materials

2. Measurements

a. Use split sample comparison results

b. Use Proficiency Testing results

c. At least 20 normal, healthy patient samples

3. Data Review

a. If split sample comparison showed acceptable agreement to comparative method used by Dade Behring Inc., use Dade Behring Inc. suggested Reference Interval.

b. If split sample comparison showed acceptable agreement with Laboratory's comparative method, use Dade Behring Inc. reference interval. If not acceptable, calculate new reference interval from regression equation.

c. If Proficiency Testing results show good agreement with Dade Behring Inc. peer groups, use Dade Behring Inc. suggested Reference Interval.

d. Calculate t-test on the means of the 20 "normal, healthy" samples processed on the instrument being validated and on the comparative instrument.

QUALITATIVE SCREENING STUDY
HELPFUL HINTS

1. Samples to use

a. Calibrators (use alternate lot from calibration lot)

OR

b. QC - avoid samples that exhibit possible matrix effects

OR

c. Proficiency Testing materials

2. Measurements

Run at least two samples once, i.e., positive and negative samples

3. Data Review

Measured result should agree with expected result except for those samples that are near the Positive/Negative cutoff. For those samples near the cut-off, it is acceptable to vary between positive and negative. See Test IFU for typical performance at the cut-off level.

LINEAR REPORTABLE RANGE STUDY

INSTRUMENT SERIAL #_____ DATE_____

METHOD_____ FLEX LOT #_____

Samples used: _____
(lot #if applicable)

Validator _____ Date _____

Supervisor _____ Date _____

Record results and graph data on next page

HELPFUL HINTS

1. **Samples to use**
   a. Calibrator/Verifier - use calibrator/verifier of varying known concentrations.
   (data can be used from calibration and include both active*and passive** calibrator points)

OR

   b. Elevated patient sample - make at least two dilutions in order to have three points

OR

   c. High QC - make at least two dilutions in order to have three points

OR

   d. High Calibrator/Verifier - make at least two dilutions in order to have three points

OR

   e. Mixtures of high and low patient samples

2. **Measurements**
   a. Run at least three points
   b. Run a minimum of two replicates per test point

3. **Data Review**
   a. Plot data and visually inspect for a straight line; set limits at each level

OR

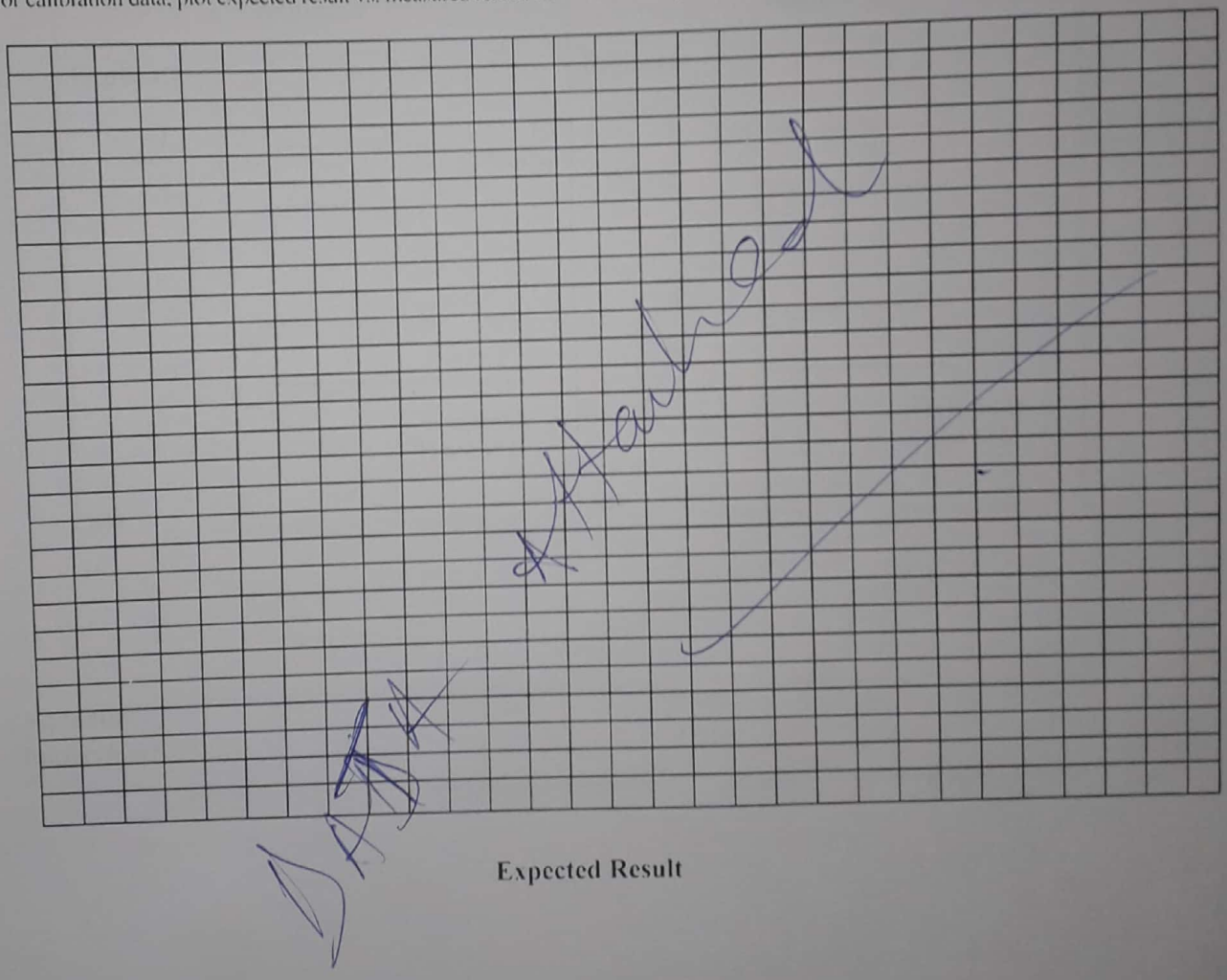
   b. Calculate statistically

* active = calibrator point used to update calibration coefficients
** passive = calibrator point not used to update calibration coefficients; processed as unknown sample

LINEAR REPORTABLE RANGE STUDY

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Expected Result	___	___	___	___	___	___
	___	___	___	___	___	___
Measured Result						
Measured Result						
	___	___	___	___	___	___
	___	___	___	___	___	___
Mean =						

Graph the Data below or attach printout from statistical program, if available.
(for calibration data, plot expected result vs. measured result; for other linearity data, plot solution vs. measured result)



PRECISION STUDY
Within-Run
HELPFUL HINTS

1. Samples to use

a. QC

- Facilitates in establishing QC range, but keep in mind possible matrix effects
- Samples should be near levels specified in IFU(Test Methodology/Insert Sheet)

b. Calibrators/Verifiers - near levels specified in QC

c. Patient Samples - near levels specified in IFU

2. Measurements

a. Run in groups of five in order to compare to stated limits in Quality Control section of test methodology

b. Run one or two levels

3. Data Review

Compare your 5-test SD and/or CV to stated limits in Quality Control section of IFU. Your results should be *less than* what is stated

If your results are *greater than* stated limits, this may indicate a system malfunction and should be investigated before reporting patient results.

VISHWARAJ HOSPITAL
16:21 Jul 19 2019

TEST REPORT

Patient: LIN1
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 16:03 Jul 19 2019

Position: 9
Segment: B

TEST	RESULT	REF. INTERVAL	UNITS
GLUC	-6 LO	assay range	mg/dL
GLUC	0 LO	73-97	mg/dL
CRE2	-0.09 LO	assay range	mg/dL
CRE2	-0.08 LO	assay range	mg/dL
GLUC mean:	-2.70	sd:4.412	cv:-163.
CRE2 mean:	-0.08	sd:0.008	cv:-9.82

VISHWARAJ HOSPITAL
15:40 Jul 19 2019

TEST REPORT

Patient: LIN1.5
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:32 Jul 19 2019

Position: 2
Segment: F

TEST	RESULT	REF. INTERVAL	UNITS
GLUC	142 HI	73-97	mg/dL
GLUC	142 HI	73-97	mg/dL
CRE2	5.47 HI	2.18-3.03	mg/dL
GLUC	142 HI	73-97	mg/dL
GLUC	140 HI	73-97	mg/dL
CRE2	5.35 HI	2.18-3.03	mg/dL
CRE2	5.34 HI	2.18-3.03	mg/dL
CRE2	5.34 HI	2.18-3.03	mg/dL
GLUC	138 HI	73-97	mg/dL
GLUC	137 HI	73-97	mg/dL
CRE2	5.32 HI	2.18-3.03	mg/dL
CRE2	5.33 HI	2.18-3.03	mg/dL
GLUC mean:	140.15	sd:2.113	cv:1.51
CRE2 mean:	5.36	sd:0.056	cv:1.04

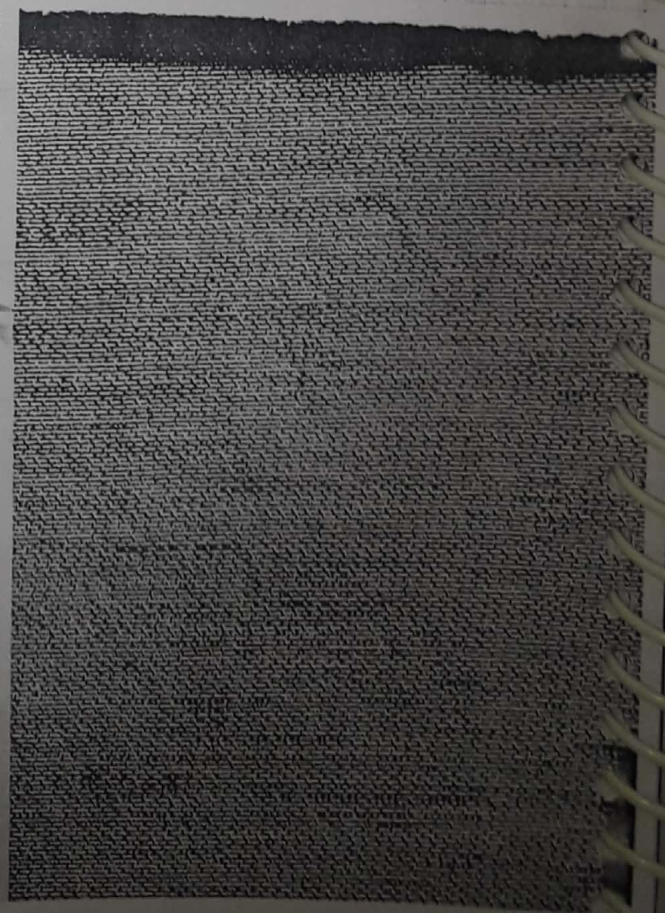
VISHWARAJ HOSPITAL
15:42 Jul 19 2019

TEST REPORT

Patient: LIN2
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:33 Jul 19 2019

Position: 3
Segment: F

TEST	RESULT	REF. INTERVAL	UNITS
GLUC	269 HI	73-97	mg/dL
GLUC	270 HI	73-97	mg/dL
CRE2	10.73 HI	2.18-3.03	mg/dL
GLUC	271 HI	73-97	mg/dL
GLUC	272 HI	73-97	mg/dL
CRE2	10.88 HI	2.18-3.03	mg/dL
GLUC	270 HI	73-97	mg/dL
GLUC	274 HI	73-97	mg/dL
GLUC mean:	271.09	sd:1.817	cv:0.60
CRE2 mean:	10.70	sd:0.032	cv:0.30



VISHWARAJ HOSPITAL
15:42 Jul 19 2019

TEST REPORT

Patient: LINP.5
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:33 Jul 19 2019

Position: 4
Segment: F

TEST	RESULT	REF. INTERVAL	UNITS
CRE2	16.26 HI	2.18-3.03	mg/dL
GLUC	409 HI	73-97	mg/dL
GLUC	406 HI	73-97	mg/dL
CRE2	16.22 HI	2.18-3.03	mg/dL
CRE2	16.43 HI	2.18-3.03	mg/dL
CRE2	16.48 HI	2.18-3.03	mg/dL
CRE2	16.13 HI	2.18-3.03	mg/dL
CRE2	16.17 HI	2.18-3.03	mg/dL
GLUC	mean:407.11	sd:2.198	cv:0.54
CRE2	mean:16.28	sd:0.142	cv:0.87

VISHWARAJ HOSPITAL
15:44 Jul 19 2019

TEST REPORT

Patient: LIN3
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:33 Jul 19 2019

Position: 5
Segment: F

TEST	RESULT	REF. INTERVAL	UNITS
GLUC	537 HI	assay range	mg/dL
GLUC	533 HI	assay range	mg/dL
CRE2	21.44 HI	assay range	mg/dL
CRE2	21.73 HI	assay range	mg/dL
GLUC	mean:536.02	sd:3.142	cv:0.59
CRE2	mean:21.58	sd:0.200	cv:0.93

VISHWARAJ HOSPITAL
15:47 Jul 19 2019

TEST REPORT

Patient: LIN0
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:37 Jul 19 2019

Position: 1
Segment: D

TEST	RESULT	REF. INTERVAL	UNITS
AST	7 LO	35-51	U/L
AST	5 LO	35-51	U/L
AST mean:	6.22	sd:1.155	cv:18.57

VISHWARAJ HOSPITAL
15:48 Jul 19 2019

TEST REPORT

Patient: LIN1
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:37 Jul 19 2019

Position: 2
Segment: D

TEST	RESULT	REF. INTERVAL	UNITS
AST	36	35-51	U/L
AST	34 LO	35-51	U/L
AST	36	35-51	U/L
AST	36	35-51	U/L
AST	36	35-51	U/L
AST	36	35-51	U/L
AST mean:	35.77	sd:0.844	cv:2.36

VISHWARAJ HOSPITAL
15:49 Jul 19 2019

TEST REPORT

Patient: LIN1.5
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:38 Jul 19 2019

Position: 3
Segment: D

TEST	RESULT	REF. INTERVAL	UNITS
AST	245 HI	35-51	U/L
AST	245 HI	35-51	U/L
AST mean:	244.92	sd:0.505	cv:0.21

VISHWARAJ HOSPITAL
15:49 Jul 19 2019

TEST REPORT

Patient: LIN2
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:38 Jul 19 2019

Position: 4
Segment: D

TEST	RESULT	REF. INTERVAL	UNITS
AST	437 HI	35-51	U/L
AST	433 HI	35-51	U/L
AST mean:	434.92	sd:2.606	cv:0.60

VISHWARAJ HOSPITAL
15:49 Jul 19 2019

TEST REPORT

Patient: LIN2.5
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:38 Jul 19 2019

Position: 5
Segment: D

TEST	RESULT	REF. INTERVAL	UNITS
AST	645 HI	35-51	U/L
AST	648 HI	35-51	U/L
AST	mean:646.65	sd:2.897	cv:0.45

VISHWARAJ HOSPITAL
15:50 Jul 19 2019

TEST REPORT

Patient: LIN3
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:38 Jul 19 2019

Position: 6
Segment: D

TEST	RESULT	REF. INTERVAL	UNITS
AST	857 HI	35-51	U/L
AST	848 HI	35-51	U/L
AST	849 HI	35-51	U/L
AST	849 HI	35-51	U/L
AST	851 HI	35-51	U/L
AST	846 HI	35-51	U/L
AST	mean:849.84	sd:3.849	cv:0.45

VISHWARAJ HOSPITAL

15:42 Jul 19 2019

TEST REPORT

Patient: LIN3
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:26 Jul 19 2019

Position: 6
Segment: 8

TEST	RESULT	REF. INTERVAL	UNITS
TP	15.7 HI	assay range	g/dL
TP	15.6 HI	assay range	g/dL
ALB	8.25 HI	assay range	g/dL
ALB	8.27 HI	assay range	g/dL
ALB	mean:8.26	sd:0.016	cv:0.19
TP	mean:15.65	sd:0.133	cv:0.85

VISHWARAJ HOSPITAL
15:25 Jul 19 2019

TEST REPORT

Patient: LIN0
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:05 Jul 19 2019

Position: 9
Segment: D

TEST	RESULT	REF. INTERVAL	UNITS
TP	-0.2 LO	assay range	g/dL
TP	-0.2 LO	assay range	g/dL
ALB	-0.08 LO	assay range	g/dL
ALB	-0.08 LO	assay range	g/dL
ALB	mean:-0.08	sd:0.002	cv:-1.95
TP	mean:-0.23	sd:0.017	cv:-7.45

VISHWARAJ HOSPITAL
16:25 Jul 19 2019

TEST REPORT

Patient: LIN1
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 16:05 Jul 19 2019

Position: 10
Segment: D

TEST	RESULT	REF. INTERVAL	UNITS
TP	0.8 LO	assay range	g/dL
TP	1.3 LO	assay range	g/dL
ALB	0.39 LO	assay range	g/dL
ALB	0.39 LO	assay range	g/dL
ALB	0.39 LO	assay range	g/dL
ALB	0.40 LO	assay range	g/dL
ALB	0.40 LO	assay range	g/dL
ALB	0.40 LO	assay range	g/dL
ALB	mean:0.39	sd:0.007	cv:1.88
TP	mean:1.02	sd:0.334	cv:32.70

PRINT RESULTS

Patient: LIN1.5
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:25 Jul 19 2019

Position: 3
Segment: B

TEST	RESULT	REF. INTERVAL	UNITS
TP	5.2 LO	7.7-8.8	g/dL
TP	5.0 LO	7.7-8.8	g/dL
ALB	2.32 LO	3.69-4.37	g/dL
ALB	2.34 LO	3.69-4.37	g/dL
ALB	mean:2.33	sd:0.010	cv:0.42
TP	mean:5.09	sd:0.103	cv:2.03

VISHWARAJ HOSPITAL
15:40 Jul 19 2019

TEST REPORT

Patient: LIN2
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:25 Jul 19 2019

Position: 4
Segment: B

TEST	RESULT	REF. INTERVAL	UNITS
TP	7.7	7.7-8.8	g/dL
TP	7.6 LO	7.7-8.8	g/dL
TP	7.6 LO	7.7-8.8	g/dL
TP	7.6 LO	7.7-8.8	g/dL
TP	7.6 LO	7.7-8.8	g/dL
TP	8.2	7.7-8.8	g/dL
ALB	4.17	3.69-4.37	g/dL
ALB	4.14	3.69-4.37	g/dL
ALB	4.13	3.69-4.37	g/dL
ALB	4.13	3.69-4.37	g/dL
ALB	4.16	3.69-4.37	g/dL
ALB	4.13	3.69-4.37	g/dL
ALB	mean:4.14	sd:0.015	cv:0.36
TP	mean:7.70	sd:0.262	cv:3.40

VISHWARAJ HOSPITAL

15:41 Jul 19 2019

TEST REPORT

Patient: LIN2.5
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:26 Jul 19 2019

Position: 5
Segment: B

TEST	RESULT	REF. INTERVAL	UNITS
TP	12.1 HI	assay range	g/dL
TP	11.7 HI	7.7-8.8	g/dL
ALB	6.31 HI	3.69-4.37	g/dL
ALB	6.31 HI	3.69-4.37	g/dL
ALB	mean:6.31	sd:0.004	cv:0.07
TP	mean:11.94	sd:0.292	cv:2.44

VISHWARAJ HOSPITAL

16:24 Jul 19 2019

TEST REPORT

Patient: LIN2.5
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:59 Jul 19 2019

Position: 4
Segment: F

TEST	RESULT	REF. INTERVAL	UNITS
DBI	14.1 HI	0.1-0.3	mg/dL
TBI	19.6 HI	0.6-1.1	mg/dL
DBI	14.1 HI	0.1-0.3	mg/dL
DBI	14.2 HI	0.1-0.3	mg/dL
DBI	14.3 HI	0.1-0.3	mg/dL
DBI	14.2 HI	0.1-0.3	mg/dL
DBI	14.2 HI	0.1-0.3	mg/dL
TBI	19.6 HI	0.6-1.1	mg/dL
TBI	19.5 HI	0.6-1.1	mg/dL
TBI	19.3 HI	0.6-1.1	mg/dL
TBI	19.5 HI	0.6-1.1	mg/dL
TBI	19.3 HI	0.6-1.1	mg/dL
TBI	mean:19.45	sd:0.141	cv:0.73
DBI	mean:14.18	sd:0.064	cv:0.45

VISHWARAJ HOSPITAL
16:15 Jul 19 2019

TEST REPORT

Patient: LIN2
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:59 Jul 19 2019

Position: 3
Segment: F

TEST	RESULT	REF. INTERVAL	UNITS
DBI	7.7 HI	0.1-0.3	mg/dL
DBI	7.7 HI	0.1-0.3	mg/dL
TBI	10.3 HI	0.6-1.1	mg/dL
TBI	10.4 HI	0.6-1.1	mg/dL
TBI	mean:10.37	sd:0.070	cv:0.67
DBI	mean:7.72	sd:0.011	cv:0.15

VISHWARAJ HOSPITAL
16:16 Jul 19 2019

TEST REPORT

Patient: LIN3
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:59 Jul 19 2019

Position: 5
Segment: F

TEST	RESULT	REF. INTERVAL	UNITS
DBI	19.6 HI	assay range	mg/dL
DBI	19.5 HI	assay range	mg/dL
TBI	28.8 HI	assay range	mg/dL
TBI	29.0 HI	assay range	mg/dL
TBI	mean:28.94	sd:0.137	cv:0.47
DBI	mean:19.54	sd:0.062	cv:0.32

VISHWARAJ HOSPITAL
16:12 Jul 19 2019

TEST REPORT

Patient: LIN1
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:58 Jul 19 2019

Position: 1
Segment: F

TEST	RESULT	REF. INTERVAL	UNITS
DBI	0.0 LO	assay range	mg/dL
DBI	0.0 LO	assay range	mg/dL
TBI	0.0 LO	assay range	mg/dL
TBI	0.0 LO	assay range	mg/dL
TBI	mean:-0.02	sd:0.007	cv:-33.9
DBI	mean:0.00	sd:0.000	cv:11.58

VISHWARAJ HOSPITAL
16:13 Jul 19 2019

TEST REPORT

Patient: LIN1.5
Sample No.:
Location:
Sample: SerumQC1
Priority: XQC
Entered: 15:59 Jul 19 2019

Position: 2
Segment: F

TEST	RESULT	REF. INTERVAL	UNITS
DBI	3.4 HI	0.1-0.3	mg/dL
TBI	4.0 HI	0.6-1.1	mg/dL
TBI	4.0 HI	0.6-1.1	mg/dL
TBI	3.9 HI	0.6-1.1	mg/dL
TBI	4.0 HI	0.6-1.1	mg/dL
TBI	3.9 HI	0.6-1.1	mg/dL
TBI	3.9 HI	0.6-1.1	mg/dL
DBI	3.3 HI	0.1-0.3	mg/dL
DBI	3.3 HI	0.1-0.3	mg/dL
DBI	3.3 HI	0.1-0.3	mg/dL
DBI	3.3 HI	0.1-0.3	mg/dL
DBI	3.3 HI	0.1-0.3	mg/dL
TBI	mean:3.94	sd:0.018	cv:0.47
DBI	mean:3.33	sd:0.027	cv:0.82

Dade Behring Dimension® Report for ALB Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	FA2027
Calib. LN:	0DD036

Coefficients:	
C0:	-1.7864
C1:	0.0207

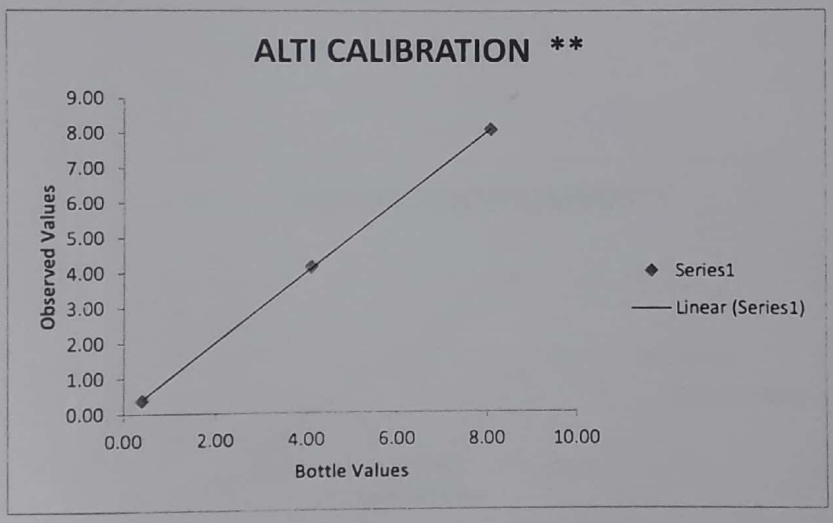
Calibrations Samples

Sample	Calib. BV	Obs. Value
Cal: Level 1	0.40	0.37
Cal: Level 1	0.40	0.37
Cal: Level 1	0.40	0.39
Cal: Level 2	4.10	4.12
Cal: Level 2	4.10	4.15
Cal: Level 2	4.10	4.16
Cal: Level 3	8.10	8.09
Cal: Level 3	8.10	8.06
Cal: Level 4	8.10	8.09

Slope (m)	1.001
Intercept (b)	-0.002
Corr Coef (r)	1.000

Acceptable calibration specifications:

Slope	**-**
Intercept	Close to zero or clinically insignificant



Accepted By _____ Date _____

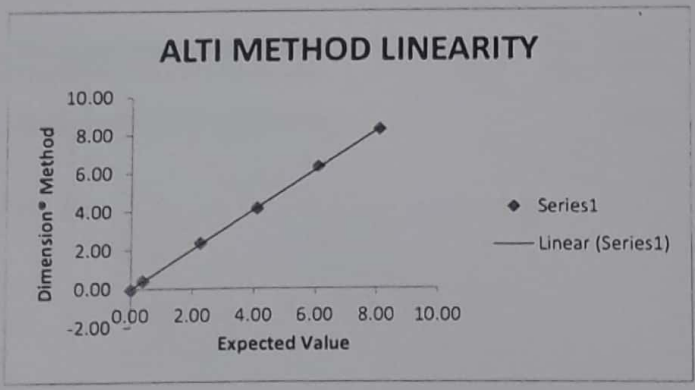
Dade Behring Dimension® Report for ALB Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	FA2027
Calib. LN:	0DD036

Coefficients:	
C0:	-11.843
C1:	-3.672

Linearity Test Samples (Values are in **)

Sample	Expected	Dimension®
L0	0.00	-0.08
L0	0.00	-0.08
L1	0.40	0.39
L1	0.40	0.39
L1	0.40	0.39
L1	0.40	0.40
L1	0.40	0.40
L1.5	2.25	2.32
L1.5	2.25	2.34
L2	4.10	4.17
L2	4.10	4.14
L2	4.10	4.13
L2	4.10	4.13
L2	4.10	4.13
L2.5	6.10	6.31
L2.5	6.10	6.31
L3	8.10	8.25
L3	8.10	8.27



Linear Regression Statistics

No. of Samples	18
Slope	1.0271
Y-Intercept	-0.03
Correlation (r)	0.9999
Syx	0.05

Accepted By _____ Date _____

Dade Behring Dimension® Report for ALB Method

Date: 19th July 2019
Site: VISHWARAJ HOSPITAL, LONI K, PUNE
Address: Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator: Mr. Kiran
Inst. ID: DE271193
Flex LN: FA2027
Calib. LN: 0DD036

Precision Data Values in **

Sample	Result	Mean	SD	CV
L0	-0.08			
L0	-0.08	-0.1	0.000	
L1	0.39			
L1	0.39			
L1	0.39			
L1	0.40			
L1	0.40	0.4	0.005	1.4%
L1.5	2.32			
L1.5	2.34	2.3	0.014	0.6%
L2	4.17			
L2	4.14			
L2	4.13			
L2	4.13			
L2	4.13	4.1	0.017	0.4%
L2.5	6.31			
L2.5	6.31	6.3	0.000	0.0%
L3	8.25			
L3	8.27	6.7	1.715	0.5%

The assay range for this method is:	0.60	to	8.00	g/dL
The linearity for this method is:	-0.08	to	8.10	g/dL
Analytical Sensitivity Verification			-0.08	g/dL

Accepted By _____ Date _____

Dade Behring Dimension® Report for TP Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K. PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	EA2042
Calib. LN:	0DD036

Coefficients:	
C0:	3.7566
C1:	0.0245

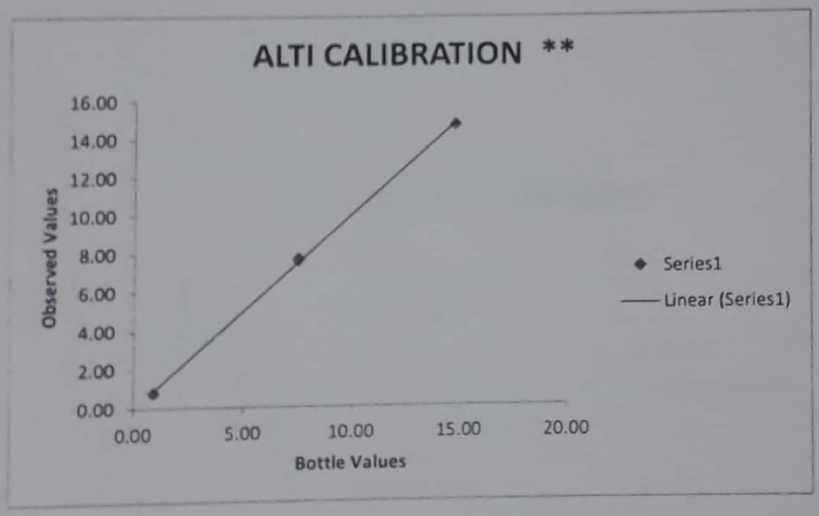
Calibrations Samples

Sample	Calib. BV	Obs. Value
Cal: Level 1	0.90	0.80
Cal: Level 1	0.90	0.80
Cal: Level 1	0.90	0.80
Cal: Level 2	7.50	7.70
Cal: Level 2	7.50	7.70
Cal: Level 2	7.50	7.60
Cal: Level 3	14.80	14.70
Cal: Level 3	14.80	14.70
Cal: Level 4	14.80	14.70

Slope (m)	1.002
Intercept (b)	-0.015
Corr Coef (r)	1.000

Acceptable calibration specifications:

Slope	0.97 - 1.03
Intercept	Close to zero or clinically insignificant



Accepted By _____ Date _____

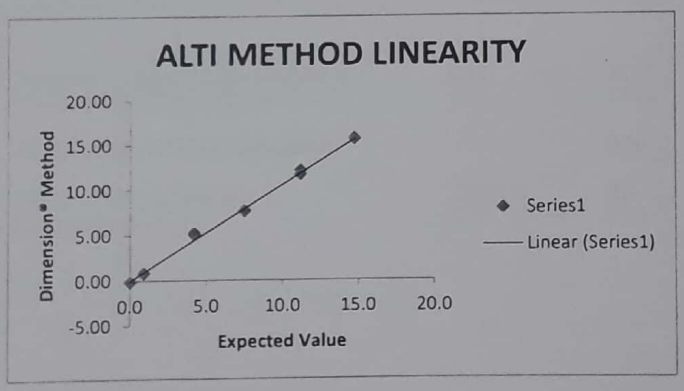
Dade Behring Dimension® Report for TP Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	EA2042
Calib. LN:	0DD036

Coefficients:	
C0:	3.7566
C1:	0.0245

Linearity Test Samples (Values are in g/dL)

Sample	Expected	Dimension®
L0	0.0	-0.20
L0	0.0	-0.20
L1	0.9	0.80
L1	0.9	0.80
L1.5	4.2	5.20
L1.5	4.2	5.00
L2	7.5	7.70
L2	7.5	7.60
L2	7.5	7.60
L2	7.5	7.60
L2	7.5	7.60
L2.5	11.2	12.10
L2.5	11.2	11.70
L3	14.8	15.70
L3	14.8	15.60



Linear Regression Statistics	
No. of Samples	15
Slope	1.0585
Y-Intercept	-0.06
Correlation (r)	0.9980
Syx	0.35

Accepted By _____ Date _____

Dade Behring Dimension® Report for TP Method

Date: 19th July 2019
Site: VISHWARAJ HOSPITAL, LONI K, PUNE
Address: Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator: Mr. Kiran
Inst. ID: DE271193
Flex LN: EA2042
Calib. LN: 0DD036

Precision Data Values in **

Sample	Result	Mean	SD	CV
L0	-0.20			
L0	-0.20	-0.2	0.000	
L1	0.80			
L1	0.80	0.8	0.000	0.0%
L1.5	5.20			
L1.5	5.00	5.1	0.141	2.8%
L2	7.70			
L2	7.60			
L2	7.60			
L2	7.60			
L2	7.60	7.6	0.045	0.6%
L2.5	12.10			
L2.5	11.70	11.9	0.283	2.4%
L3	15.70			
L3	15.60	15.7	0.071	0.5%

The assay range for this method is:	2.00	to	12.00	g/dL
The linearity for this method is:	-0.20	to	15.70	g/dL
Analytical Sensitivity Verification			0.00	g/dL
The precision guidelines for this method are:	CONC. 6.06	<	SD 0.09	g/dL

Accepted By _____ Date _____

Dade Behring Dimension® Report for AST Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	GA2096
Calib. LN:	0GJ061

Coefficients:	
C0:	2.000
C1:	-3.537

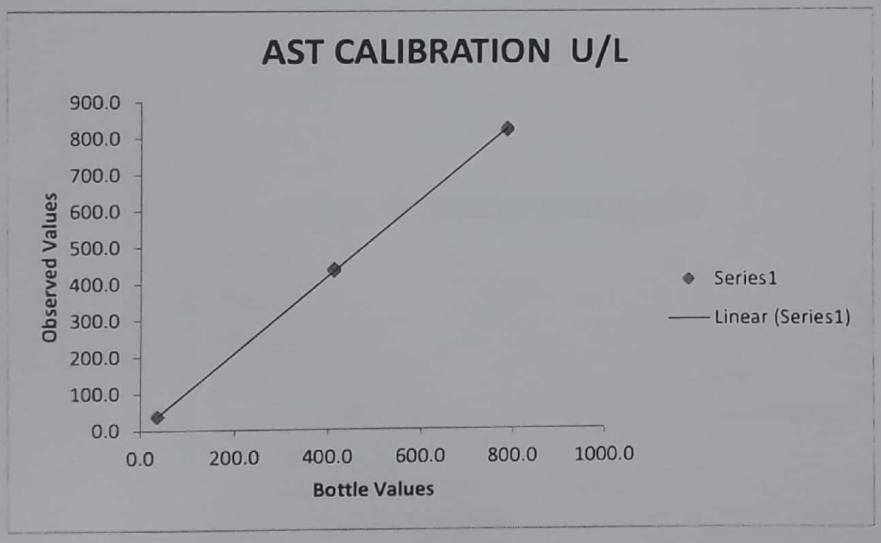
Calibrations Samples

Sample	Calib. BV	Obs. Value
Cal: Level 1	36.0	38.0
Cal: Level 1	36.0	35.0
Cal: Level 1	36.0	36.0
Cal: Level 2	411.0	431.0
Cal: Level 2	411.0	437.0
Cal: Level 2	411.0	432.0
Cal: Level 3	785.0	816.0
Cal: Level 3	785.0	823.0
Cal: Level 3	785.0	824.0

Slope (m)	1.048
Intercept (b)	-0.002
Corr Coef (r)	1.000

Acceptable calibration specifications:

Slope	0.9 - 1.1
Intercept	Close to zero or clinically insignificant



Accepted By _____ **Date** _____

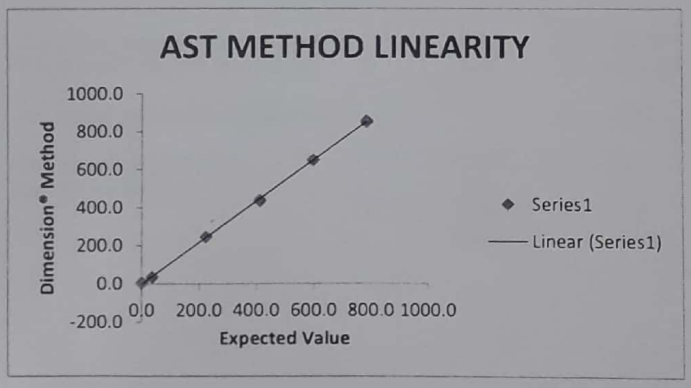
Dade Behring Dimension® Report for AST Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	GA2096
Calib. LN:	0GJ061

Coefficients:	
C0:	2.000
C1:	-3.537

Linearity Test Samples (Values are in U/L)

Sample	Expected	Dimension®
L0	0.0	7.0
L0	0.0	5.0
L1	36.0	36.0
L1	36.0	34.0
L1	36.0	36.0
L1	36.0	36.0
L1	36.0	36.0
L1.5	223.5	245.0
L1.5	223.5	245.0
L2	411.0	437.0
L2	411.0	433.0
L2.5	598.0	645.0
L2.5	598.0	649.0
L3	785.0	857.0
L3	785.0	848.0
L3	785.0	849.0
L3	785.0	849.0
L3	785.0	851.0



Linear Regression Statistics

No. of Samples	18
Slope	1.0833
Y-Intercept	-1.06
Correlation (r)	0.9999
Syx	5.07

Accepted By _____ **Date** _____

Dade Behring Dimension® Report for AST Method

Date: 19th July 2019
Site: VISHWARAJ HOSPITAL, LONI K, PUNE
Address: Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator: Mr. Kiran
Inst. ID: DE271193
Flex LN: GA2096
Calib. LN: 0GJ061

Precision Data Values in U/L

Sample	Result	Mean	SD	CV
L0	7.0			
L0	5.0	6.0	1.414	23.6%
L1	36.0			
L1	34.0			
L1	36.0			
L1	36.0			
L1	36.0	35.6	0.894	2.5%
L1.5	245.0			
L1.5	245.0	245.0	0.000	0.0%
L2	437.0			
L2	433.0	435.0	2.828	0.7%
L2.5	645.0			
L2.5	649.0	647.0	2.828	0.4%
L3	857.0			
L3	848.0			
L3	849.0			
L3	849.0			
L3	851.0	850.8	3.633	0.4%

The assay range for this method is:	0.00	to	857.00	U/L
The linearity for this method is:	2.88	to	787.13	U/L
Analytical Sensitivity Verification			2.88	U/L
The precision guidelines for this method are:	CONC.		SD	
	40.00	<	2.50	U/L
	440.00	<	8.00	U/L
	830.00	<	15.00	U/L

Accepted By _____ Date _____

Dade Behring Dimension® Report for CRE2 Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	GB2075
Calib. LN:	0LD077

Coefficients:	
C0:	-0.3650
C1:	0.0779

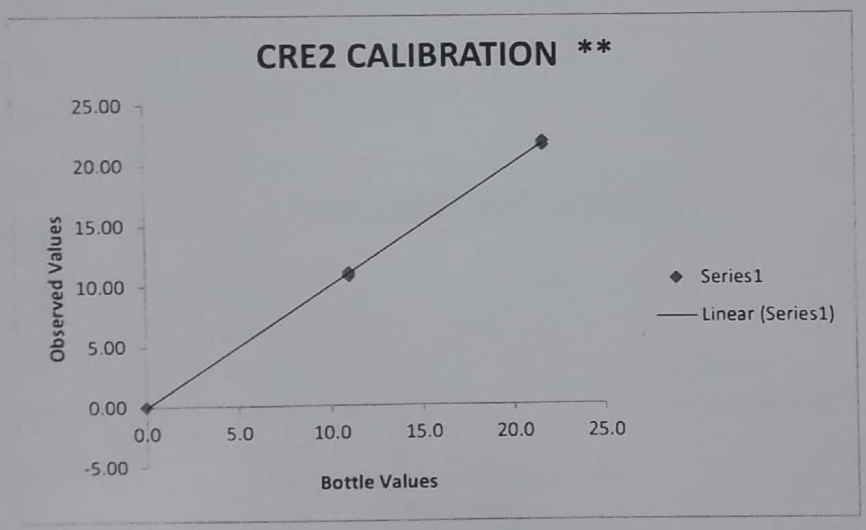
Calibrations Samples

Sample	Calib. BV	Obs. Value
Cal: Level 1	0.0	0.01
Cal: Level 1	0.0	0.01
Cal: Level 1	0.0	0.00
Cal: Level 2	10.97	10.69
Cal: Level 2	10.97	10.75
Cal: Level 2	10.97	10.98
Cal: Level 3	21.61	21.84
Cal: Level 3	21.61	21.74
Cal: Level 3	21.61	21.49

Slope (m)	1.003
Intercept (b)	-0.061
Corr Coef (r)	1.000

Acceptable calibration specifications:

Slope	**-**
Intercept	Close to zero or clinically insignificant



Accepted By _____ **Date** _____

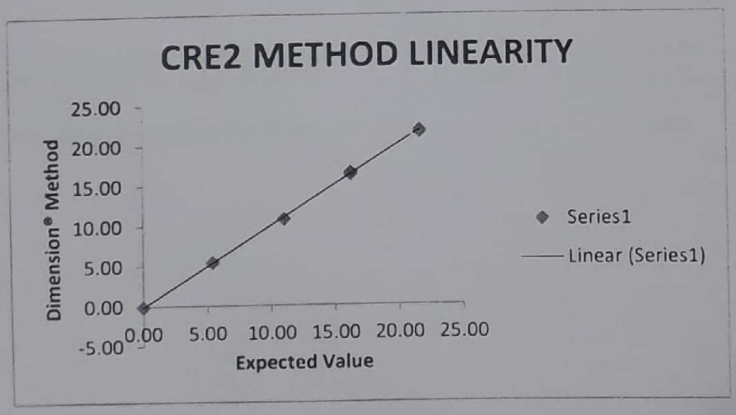
Dade Behring Dimension® Report for CRE2 Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	GB2075
Calib. LN:	0LD077

Coefficients:	
C0:	-0.3650
C1:	0.0779

Linearity Test Samples (Values are in **)

Sample	Expected	Dimension®
L1	0.00	-0.09
L1	0.00	-0.08
L1.5	5.40	5.35
L1.5	5.40	5.34
L1.5	5.40	5.34
L1.5	5.40	5.34
L1.5	5.40	5.33
L2	10.97	10.73
L2	10.97	10.68
L2.5	16.20	16.26
L2.5	16.20	16.22
L2.5	16.20	16.43
L2.5	16.20	16.17
L2.5	16.20	16.48
L3	21.61	21.44
L3	21.61	21.73



Linear Regression Statistics	
No. of Samples	16
Slope	1.0077
Y-Intercept	-0.11
Correlation (r)	0.9998
Syx	0.14

Accepted By _____ Date _____

Dade Behring Dimension® Report for CRE2 Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	GB2075
Calib. LN:	0LD077

Precision Data Values in **

Sample	Result	Mean	SD	CV
L1	-0.09			
L1	-0.08	-0.1	0.007	
L1.5	5.35			
L1.5	5.34			
L1.5	5.34			
L1.5	5.34			
L1.5	5.33	5.3	0.007	0.1%
L2	10.73			
L2	10.68	10.7	0.035	0.3%
L2.5	16.26			
L2.5	16.22			
L2.5	16.43			
L2.5	16.17			
L2.5	16.48	16.3	0.136	0.8%
L3	21.44			
L3	21.73	21.6	0.205	1.0%

The assay range for this method is:	0.00	to	21.00	mg/dl
The linearity for this method is:	0.00	to	21.73	mg/dl
Analytical Sensitivity Verification			0.00	mg/dl

Accepted By _____ Date _____

Dade Behring Dimension® Report for CRE2 Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	FB2144
Calib. LN:	0GD046

Coefficients:	
C0:	0.0377
C1:	0.0757

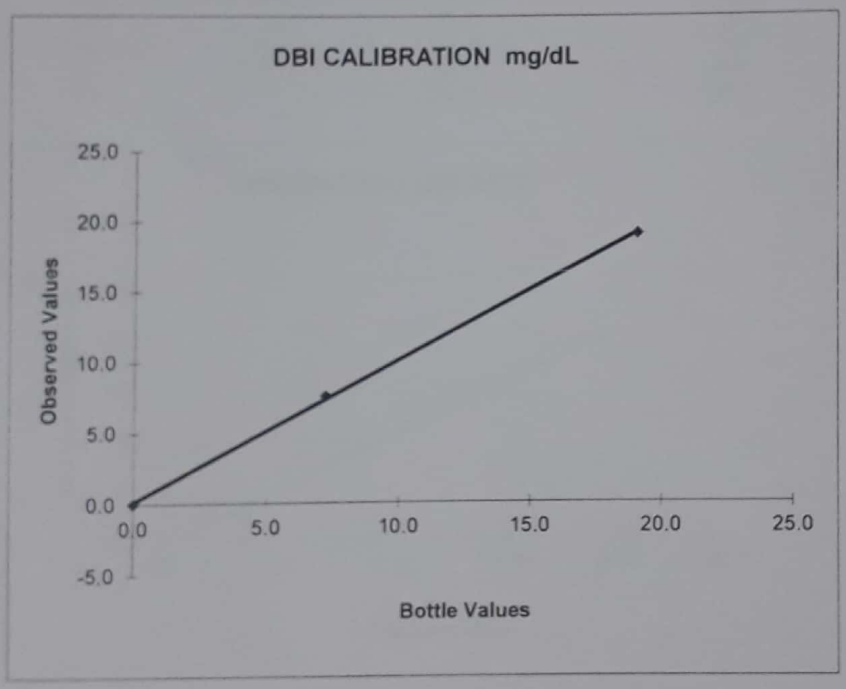
Calibrations Samples

Sample	Calib. BV	Obs. Value
Cal: Level 1	0.0	0.0
Cal: Level 1	0.0	0.0
Cal: Level 1	0.0	0.0
Cal: Level 2	7.2	7.5
Cal: Level 2	7.2	7.5
Cal: Level 2	7.2	7.5
Cal: Level 3	19.1	19.0
Cal: Level 3	19.1	19.0
Cal: Level 3	19.1	19.0

Slope (m)	0.994
Intercept (b)	0.131
Corr Coef (r)	1.000

Acceptable calibration specifications:

Slope	0.97 - 1.03
Intercept	Close to zero or clinically insignificant



Accepted By _____ Date _____

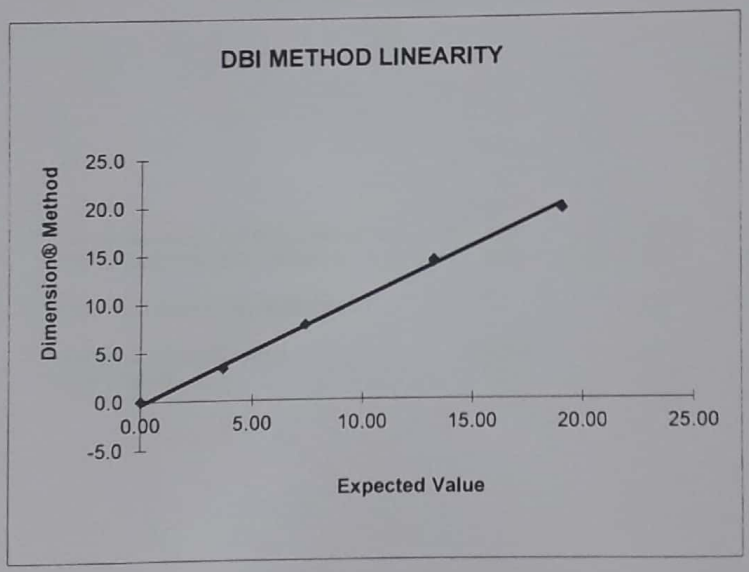
Dade Behring Dimension® Report for CRE2 Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	FB2144
Calib. LN:	0GD046

Coefficients:	
C0:	0.0377
C1:	0.0757

Linearity Test Samples (Values are in mg/dL)

Sample	Expected	Dimension®
L1	0.00	0.0
L1	0.00	0.0
L1.5	3.70	3.3
L1.5	3.70	3.3
L1.5	3.70	3.3
L1.5	3.70	3.3
L1.5	3.70	3.3
L2	7.40	7.7
L2	7.40	7.7
L2.5	13.25	14.1
L2.5	13.25	14.1
L2.5	13.25	14.2
L2.5	13.25	14.3
L2.5	13.25	14.2
L3	19.10	19.6
L3	19.10	19.5



Linear Regression Statistics	
No. of Samples	16
Slope	1.0667
Y-Intercept	-0.31
Correlation (r)	0.9985
Syx	0.38

Accepted By _____ Date _____

Dade Behring Dimension® Report for CRE2 Method

Date: 19th July 2019
Site: VISHWARAJ HOSPITAL, LONI K, PUNE
Address: Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator: Mr. Kiran
Inst. ID: DE271193
Flex LN: FB2144
Calib. LN: 0GD046

Precision Data Values in mg/dL

Sample	Result	Mean	SD	CV
L1	0.0			
L1	0.0	0.0	0.013	
L1.5	3.3			
L1.5	3.3			
L1.5	3.3			
L1.5	3.3			
L1.5	3.3	3.3	0.000	0.0%
L2	7.7			
L2	7.7	7.7	0.000	0.0%
L2.5	14.1			
L2.5	14.1			
L2.5	14.2			
L2.5	14.3			
L2.5	14.2	14.2	0.084	0.6%
L3	19.6			
L3	19.5	19.6	0.071	0.4%

The assay range for this method is:	0.05	to	16.00	mg/dL
The linearity for this method is:	0.00	to	19.10	mg/dL
Analytical Sensitivity Verification			0.00	mg/dL
The precision guidelines for this method are:	CONC.		SD	
	0.60	<	0.06	mg/dL
	16.00	<	0.34	mg/dL

Accepted By _____ Date _____

Dade Behring Dimension® Report for TBI Method

Date: 19th July 2019
Site: VISHWARAJ HOSPITAL, LONI K, PUNE
Address: Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator: Mr. Kiran
Inst. ID: DE271193
Flex LN: GA2068
Calib. LN: 0GD046

Coefficients:

C0:	-0.0763
C1:	0.0777

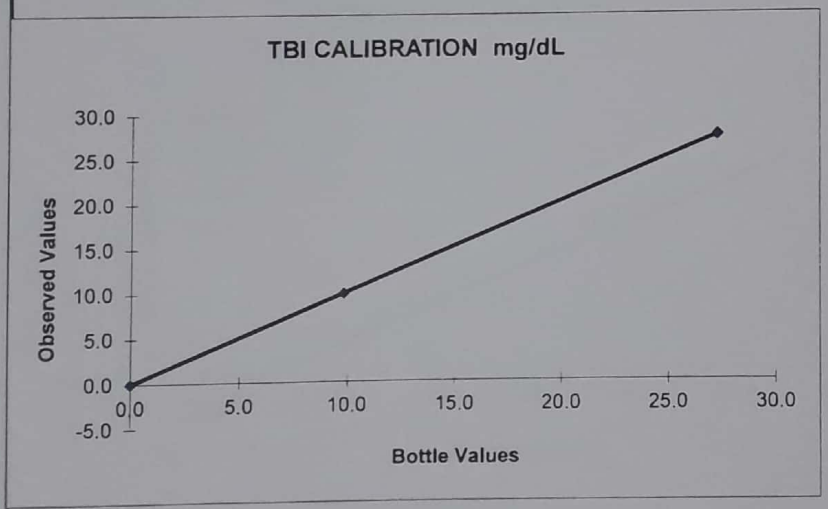
Calibrations Samples

Sample	Calib. BV	Obs. Value
Cal: Level 1	0.0	0.0
Cal: Level 1	0.0	0.0
Cal: Level 1	0.0	0.0
Cal: Level 2	9.8	9.8
Cal: Level 2	9.8	9.8
Cal: Level 2	9.8	9.8
Cal: Level 3	27.3	27.3
Cal: Level 3	27.3	27.3
Cal: Level 3	27.3	27.4

Slope (m)	1.001
Intercept (b)	-0.005
Corr Coef (r)	1.000

Acceptable calibration specifications:

Slope	0.97 - 1.03
Intercept	Close to zero or clinically insignificant



Accepted By _____ Date _____

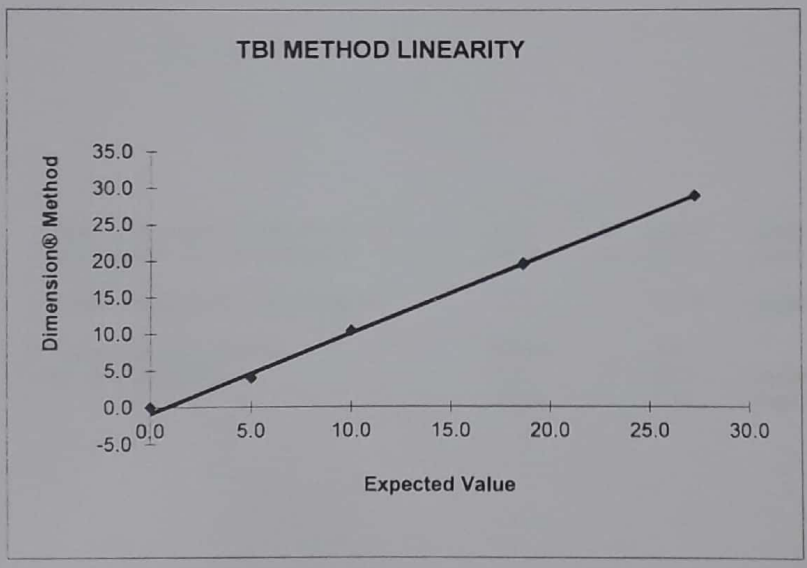
Dade Behring Dimension® Report for TBI Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	GA2068
Calib. LN:	0GD046

Coefficients:	
C0:	-0.0763
C1:	0.0777

Linearity Test Samples (Values are in mg/dL)

Sample	Expected	Dimension®
L1	0.0	0.0
L1	0.0	0.0
L1.5	5.0	4.0
L1.5	5.0	4.0
L1.5	5.0	3.9
L1.5	5.0	4.0
L1.5	5.0	3.9
L2	10.0	10.3
L2	10.0	10.4
L2.5	18.6	19.6
L2.5	18.6	19.6
L2.5	18.6	19.5
L2.5	18.6	19.3
L2.5	18.6	19.5
L3	27.3	28.8
L3	27.3	29.0



Linear Regression Statistics

No. of Samples	16
Slope	1.0911
Y-Intercept	-0.91
Correlation (r)	0.9987
Syx	0.52

Accepted By _____ Date _____

Dade Behring Dimension® Report for TBI Method

Date: 19th July 2019
Site: VISHWARAJ HOSPITAL, LONI K, PUNE
Address: Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator: Mr. Kiran
Inst. ID: DE271193
Flex LN: GA2068
Calib. LN: 0GD046

Precision Data Values in mg/dL

Sample	Result	Mean	SD	CV
L1	0.0			
L1	0.0	0.0	0.000	
L1.5	4.0			
L1.5	4.0			
L1.5	3.9			
L1.5	4.0			
L1.5	3.9	4.0	0.055	1.4%
L2	10.3			
L2	10.4	10.4	0.071	0.7%
L2.5	19.6			
L2.5	19.6			
L2.5	19.5			
L2.5	19.3			
L2.5	19.5	19.5	0.122	0.6%
L3	28.8			
L3	29.0	28.9	0.141	0.5%

The assay range for this method is:	**0.10**	**to**	**25.00**	**mg/dL**
The linearity for this method is:	**-0.10**	**to**	**27.40**	**mg/dL**
Analytical Sensitivity Verification			**-0.10**	**mg/dL**
The precision guidelines	**CONC.**		**SD**	
for this method are:	**1.10**	**<**	**0.03**	**mg/dL**
	18.80	**<**	**0.56**	**mg/dL**

Accepted By _____ **Date** _____

Dade Behring Dimension® Report for GLUC Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	GB1292
Calib. LN:	0LD077

Coefficients:	
C0:	0.265
C1:	0.907

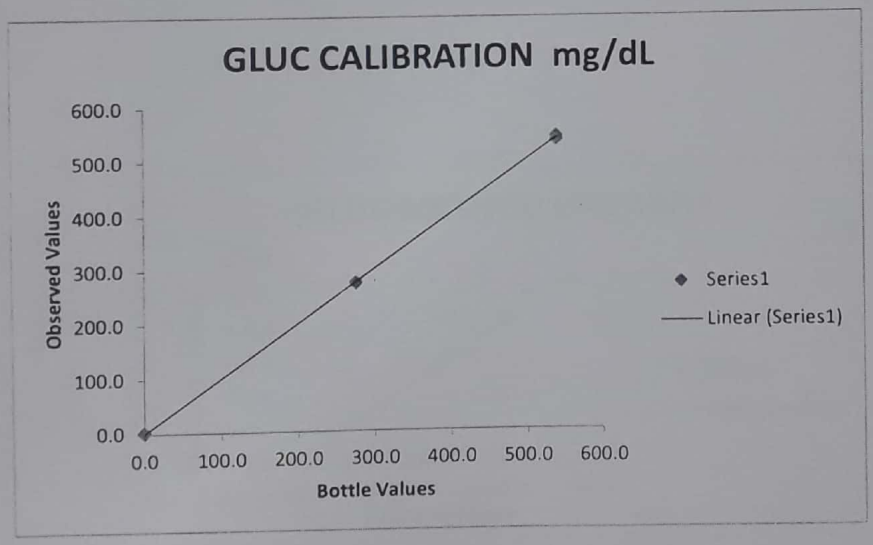
Calibrations Samples

Sample	Calib. BV	Obs. Value
Cal: Level 1	0.0	1.0
Cal: Level 1	0.0	1.0
Cal: Level 1	0.0	1.0
Cal: Level 2	274.0	273.0
Cal: Level 2	274.0	272.0
Cal: Level 2	274.0	272.0
Cal: Level 3	538.0	542.0
Cal: Level 3	538.0	540.0
Cal: Level 3	538.0	534.0

Slope (m)	0.999
Intercept (b)	0.183
Corr Coef (r)	1.000

Acceptable calibration specifications:

Slope	0.97 - 1.03
Intercept	Close to zero or clinically insignificant



Accepted By _____ **Date** _____

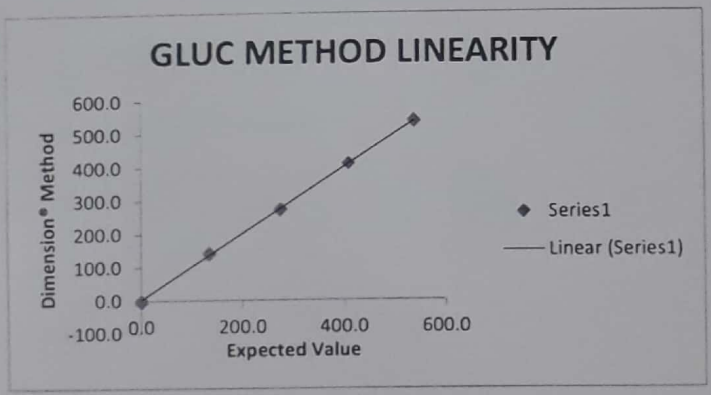
Dade Behring Dimension® Report for GLUC Method

Date:	19th July 2019
Site:	VISHWARAJ HOSPITAL, LONI K, PUNE
Address:	Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator:	Mr. Kiran
Inst. ID:	DE271193
Flex LN:	GB1292
Calib. LN:	0LD077

Coefficients:	
C0:	0.265
C1:	0.907

Linearity Test Samples (Values are in mg/dL)

Sample	Expected	Dimension®
L1	0.0	-6.0
L1	0.0	0.0
L1.5	134.5	142.0
L1.5	134.5	142.0
L1.5	134.5	142.0
L1.5	134.5	140.0
L1.5	134.5	138.0
L2	274.0	269.0
L2	274.0	270.0
L2	274.0	271.0
L2	274.0	272.0
L2	274.0	270.0
L2.5	408.5	409.0
L2.5	408.5	406.0
L3	538.0	537.0
L3	538.0	533.0



Linear Regression Statistics	
No. of Samples	16
Slope	0.9888
Y-Intercept	2.74
Correlation (r)	0.9996
Syx	4.61

Accepted By _____ **Date** _____

Dade Behring Dimension® Report for GLUC Method

Date: 19th July 2019
Site: VISHWARAJ HOSPITAL, LONI K, PUNE
Address: Rajbaug, Pune-Solapur Road, Loni Kalbhor, Pune
Operator: Mr. Kiran
Inst. ID: DE271193
Flex LN: GB1292
Calib. LN: 0LD077

Precision Data Values in mg/dL

Sample	Result	Mean	SD	CV
L1	-6.0			
L1	0.0	-3.0	4.243	
L1.5	142.0			
L1.5	142.0			
L1.5	142.0			
L1.5	140.0			
L1.5	138.0	140.8	1.789	1.3%
L2	269.0			
L2	270.0			
L2	271.0			
L2	272.0			
L2	270.0	270.4	1.140	0.4%
L2.5	409.0			
L2.5	406.0	407.5	2.121	0.5%
L3	537.0			
L3	533.0	535.0	2.828	0.5%

The assay range for this method is:	0.00	to	500.00	mg/dL
The linearity for this method is:	6.00	to	537.00	mg/dL
Analytical Sensitivity Verification			6.00	mg/dL
The precision guidelines for this method are:	CONC.		SD	
	78.00	<	4.70	mg/dL
	264.00	<	12.00	mg/dL

Accepted By _____ Date _____