Adventist HealthCare

TRAINING UPDATE

Lab Location: All Labs
Department: Core lab

Date Distributed: 2/13/26
Due Date: 2/27/26
Implementation: 2/13/26

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
AHC.QA39.8 QC Responsibilities and Review
Description of change(s):
Clarified additional responsibilities for Testing Personnel and the general supervisor, and added definitions for SDI and CVR.

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

Non-Technical SOP

Title	**QC Responsibilities and Review**	
Prepared by	Robert SanLuis	Date: 8/1/2011
Owner	Robert SanLuis, Cynthia Bowman-Gholston	Date: 12/12/2016

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

TABLE OF CONTENTS

1. PURPOSE

The performance, review, and maintenance of Quality Control are the responsibility of each person working in the laboratory. This document defines the roles of the Testing Personnel, the General Supervisor, and the Technical Supervisor to ensure that standards for Quality Control are understood and implemented every time patient samples are tested.

2. SCOPE

This document applies to all QC procedures in the laboratory. There are many aspects to managing an effective Quality Control program, some of which require daily, weekly, or monthly actions. Each of these is very important and essential to the ongoing success in our QC program's ability to identify those changes in the quality of testing that could adversely affect patient results. The overall review of QC is a shared responsibility that features unique roles as described below.

3. RESPONSIBILITY

Testing Personnel have primary responsibility for adhering to QC procedures, troubleshooting, daily maintenance, temperature/humidity monitoring and documenting corrective action on a **daily basis**, with every batch, worklist, or group of patient samples. See details in Section 5.

The **General Supervisor** has primary responsibility for the **weekly review** of QC records and information, while being available on a daily basis to assist in problem solving. See details in Section 6.

The **Technical Supervisor/Consultant** has primary responsibility for **monthly review** of QC information. See details in Section 7.

4. DEFINITIONS

Term	Definition
Coefficient of Variation (CV)	The ratio of the standard deviation to the mean. The CV reflects the extent of variability in relation to the mean of the population.
Coefficient of Variation Ratio (CVR)	The coefficient of variation ratio compares your laboratory precision for a specific test to the CV of other labs performing the same test. CVR=(Within Lab CV)/(Consensus group CV)
Imprecision	The variation of a process. This is measured by the standard deviation of the values.
Standard Deviation (SD)	A statistic used to describe the distribution or spread of data in a population that is shown to have the shape of a normal or Gaussian curve.
Standard Deviation Index (SDI)	The target SDI is 0.0, which indicates there is not any difference between the lab mean and the consensus group mean. The SDI expresses bias as increments of the standard deviation. An SDI >/= 2.0, positive or negative. (Lab Mean-Peer Mean)/Peer SD
Trend	A general change that may increase or decrease in magnitude over time.

5. TESTING PERSONNEL QC RESPONSIBILITIES

A. QC Material Management

1. Ensure that QC materials are prepared properly (including use of current lot numbers)
2. Ensure that QC materials are placed properly in the batch or worklist per the assay SOP.
3. Ensure that QC checks are completed on new lots before use.
4. Ensure that QC samples are tested in the same manner as patient samples.
5. Ensure that QC expiration date and time is updated to manufacturer guidelines, when placed into use (i.e. Coagulation Controls).

B. QC Results Review (daily/weekly)

1. Verify daily/weekly maintenance is completed and documented as assigned on time.
   a) Any delay or failure to perform daily/weekly maintenance must be documented.
   b) Once the issue causing the delay is resolved scheduled maintenance must be performed and documented.

2. Verify temperature and humidity are within range per AHC.QA12, Temperature and Humidity Quality Control.

3. Verify that all QC data are entered into the appropriate database (LIS or other QC software system) or appropriate QC tracking log, as defined in the testing SOP.
   a) Verify that all acceptable and unacceptable QC data points are recorded and captured.
   b) Verify compliance with specific QC frequency requirements, including manual QC documentation equals the requested response stated on the QC form.
   c) Verify that each QC data point designated as acceptable is within the defined tolerance limits for the assay tested.
      - Acceptable QC points require no further documentation
      - Unacceptable QC should be followed by an acceptable run prior to performing testing
   d) Verify that all QC warnings are identified and appropriately documented on the QC Summary Report (Spreadsheet).
   e) Verify that all QC failures are identified and appropriately documented in the QC software system and on QC Summary Report.
      - Data points appearing as gross outliers may be dispositioned (excluded from statistical analysis), but must remain in the QC record.
      - Verify appropriate corrective action was taken and documented including the need and/or result of Look Back when indicated (1:3S)
      - Notify supervisor and manager if Look Back failed or was not performed to determine extent of failure, necessary corrective action and potential for RQI report.
      - For testing that does not allow appropriate Look Back, assess if testing was performed and submit data for supervisor/manager review. An assessment of patient impact may be required by the medical director or designee.

   f) Verify that NO patient results were released when controls exceed acceptable limits as defined by the QC Program. Take appropriate corrective action and documentation, as specified in step 4.

4. Review patient results: checking for critical values, need for dilutions and repeats, “impossible/absurd” results that might indicate sampling errors, and population trends.

5. Evaluate the documented corrective action for each QC failure. Written corrective action must include:
   a) the control level(s) affected
   b) the QC rule(s) violated
   c) the cause of the out-of-range QC result (or adequate review of a warning)
   d) corrective action
   e) an evaluation of patient results already reported from the affected run
   f) evidence of retesting patient samples as defined in local policy, ONLY after showing acceptable QC performance has been restored
   g) signature/initials/tech ID and date, recorded by hand or electronically

6. Document that any problems or areas of concern have been discussed with the appropriate testing personnel. The corrective action tool is the laboratory Quality Variance (QV) form.

C. QC Results Out of Range (Addendum A: Troubleshooting Quality Control Issues)

1. Ensure that NO patient results are released when controls do not meet acceptable limits.
2. Ensure that all unacceptable control results are identified and documented.
3. Take appropriate action for each QC result that is out of limits, as defined in the assay SOP. These actions include:
   - Checking the other control results.
   - Determining the scope of the problem and note such information:
     - Does it affect only this batch?
     - Does it affect only part of this batch?
     - Have there been warnings in the previous batch?
4. Determine the cause of the out of range result.
5. Take appropriate corrective action.
6. Retesting the affected patient samples, ONLY after showing acceptable performance has been restored.
7. Review the situation with the supervisor or designee for the test area.
8. Make sure that all corrective actions are fully documented.

D. Release Process

1. Make sure that **all** QC data (both good and bad) are reviewed and entered into the database or appropriate QC tracking log, defined in the testing SOP.
2. Sign and date all runs and QC records for each batch, or run, or worklist.
3. Secondary review as designated by the supervisor is strongly recommended.
4. Ensure that any incomplete corrective action items on your shift are
   - Documented in writing for the next shift.
   - Discussed with your supervisor (or designee).

6. GENERAL SUPERVISOR QC RESPONSIBILITIES

(Or designated technically responsible person)

A. QC Material Management

1. Review the status of availability of QC materials and plan for crossover testing of a new lot, if necessary.
2. Review data for checkout of new lots of QC material before they are put in use (sign and date to document review).

B. Daily QC Assistance and Review

1. Be aware of the status of all testing during the shift.
2. Provide problem solving assistance to the tech as problems arise.

C. Weekly QC Results Review

1. Review to be performed every 7-10 days
2. Examine qualitative and quantitative QC data and/or patient data on a weekly basis.
   a) Perform a 1-2 week look back of all QC points for each assay using Levy-Jennings graphs, when available. Refer to Bio-Rad Unity Real Time 2.0 Chemistry procedure for details.
      1) Identify and document trends or shifts for each control level on the QC summary log.
      2) Note whether more than one control level is similarly affected.
      3) Investigate unexpected findings.
      4) Document causes and any follow-up corrective action resulting from the weekly review.
   b) Perform a 1-2 week look back of patient means, % abnormal, etc. for each assay, if defined in the assay SOP.
      1) Identify and document trends or shifts.
      2) Investigate all QC outliers and unexpected findings.
      3) Document causes and any follow-up corrective action resulting from the weekly review.
3. Review daily/weekly maintenance and Temp/Humidity records, document any failures to perform or improper documentation.
4. Prepare a summary of the daily and weekly issues utilizing the QC summary report log incorporating all the information outlined above for Daily and Weekly QC Review. Refer to Addendum B Monthly QC Review, section Monthly QC Summary Report. The weekly QC summary report is in total the Monthly QC Summary.
5. Address issues regarding quality in general with the Department Supervisor, Manager, Director and/or staff as appropriate, documenting date of communication on the QC Summary Report and complete QV/IQE.
6. The Weekly QC Summary will be e-mailed to Supervisor/Manager for review.

D. Monthly QC responsibilities

1. Consolidate the weekly reviews for a comprehensive monthly QC Summary Report. Present the QC Summary in a binder to the Supervisor/Manager no later than 12th of the following month. The binder will contain the following:
   - Peer QC data when available, noting any alerts.
   - QAP data to be added to binder when available (Chemistry QAP ready on the 17th of the month).
   - When peer data not available: Monthly QC/LJ Data with review of QC outliers and corrective action.
   - Maintenance, Temp/Humidity Records review with corrective action.
   - The end-of-month QC Summary Report (all areas must be completed)
   - A copy of QV forms listed on the end-of-month QC Summary Report, as appropriate.

   (See Appendum B at the end of the document)

7. TECHNICAL SUPERVISOR / CONSULTANT QC RESPONSIBILITIES

(Or designated technically responsible person for the department)

A. Management of Technical QC Issues

1. Ensure that each SOP contains the correct QC information, including frequency, limits and QC rules.

B. Review of QC information

1. Monthly review to be performed by the 25th of the following month.
2. Ensure that weekly QC review is being performed and documented.
3. The Supervisor/Manager will review the monthly QC Binders.
   - Document any additional corrective action needed on the monthly summary report.
4. Verify that the performance of each assay is consistent with the previous month's performance.
   a) Examine Levy-Jennings Charts, SDs, CVs, and achieved Sigma scores if available for month to month trends and imprecision.
      - Document each performance issue and a plan for improvement on the Monthly QC Summary Report.
   b) Review the previous month's documented performance issues. Evaluate the success of their improvement plans on the Monthly QC Summary Report.

5. Evaluate and compare Peer Group QC data with interlab QC data, if applicable (SDIs, CVRs, etc.).
   a) Document each performance issue and plan for improvement on the Monthly QC Summary Report.
   b) Review the previous month's documented performance issues.
      - Evaluate the success of their improvement plans.

6. Review appropriateness of QC ranges.
   Document causes / reasons for changes of QC ranges, including the fact that new ranges are based on more data on the Monthly QC Summary Report.

7. Review frequency of failures to determine the:
   a) need for fundamental problem solving and resolution or
   b) need for staff re-training or
   c) need for repair or replacement of equipment

8. Review other incident reports, such as:
   a) revised reports
   b) client-requested repeat testing
   c) Document unexpected findings and improvement plans.

9. Assemble all QC documentation for final approval signature(s) by medical director or designee.

Note: The delegated blood bank General Supervisor or designee performs applicable duties in this section.

8. RELATED DOCUMENTS

Quality Control Program, QA procedure
Authorization of Personnel and Delegation of Responsibilities, QA procedure
Quality Control Program, Blood Bank, BB procedure
Bio-Rad Unity Real Time 2.0, Chemistry procedure
Monthly QC Summary Report (AG.F368)

9. REFERENCES

- CLIA 88 Regulations
- CAP checklists (both Lab General and Specialty Checklists)
- NCCLS guideline “Statistical Quality Control for Quantitative Measurements: Principles and Definitions: C24-A (1999). [obtain from the Corporate Medical Library, Teterboro]
- QC Responsibilities, QC Best Practice Team, QDQC714v1.0, 8/14/00.
- Policy for QC Responsibilities, QC Best Practice Team, QDMOQ718v2, 12/3/18.

10. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes GEC/SGAH/WAH.QA35.000		
000	12/12/16	Update owner Header: add other sites Section 5: add other QC software and Bio-Rad SOP, replace PI with QV form Section 6: change summary due date to 12th Section 7: Add Note about Blood Bank Section 8: update SOP list, add summary form Footer: version # leading zeroes dropped due to new EDCS in use as of 10/7/13	L Barrett Z Morrow J Negado	R SanLuis
1	1/24/18	Header: updated facility Section 1: removed QD Section 3 & 7: added technical consultant Section 4: added CV & SD, removed job titles Section 8: updated titles Section 9: added new BPT SOP	L Barrett	R SanLuis
2	4/2/19	Section 7: change monthly review due date from 21st to 25th of month	L Barrett	R SanLuis
3	3/25/21	Header: changed WAH to WOMC Section 5: added expiration updating and verifying manual QC responses Section 8: updated SOP titles	L Barrett C Bowman-Gholston	R SanLuis
4	4/5/23	Header: Changed site to All Laboratories Footer: Changed SOP prefix to AHC	D Collier	R SanLuis
5	11/25/24	Section 5C Added reference to Addendum A: Troubleshooting Quality Control Issues	R SanLuis D Collier	R SanLuis
6	2/6/26	Added Addendum B: Monthly QC Review Outline	R SanLuis	R SanLuis
7	2/13/26	Section 4: Added definitions for Coefficient of Variation Ratio and Standard Deviation Index Section 5B: Added steps 1 & 2 Section 6C: Added step 3	R SanLuis	R SanLuis

11. ADDENDA AND APPENDICES

Addendum A: Troubleshooting Quality Control Issues

Addendum B: Monthly QC Review Outline

Addendum A: Troubleshooting Quality Control Issues

Troubleshooting Quality Issues	Purpose	Principle	Function
Quality Control	Review the LJ against internal ranges and peer group ranges. The use of a LJ is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results	To ensure the QC is within range, review all levels of QC and compare with laboratory established range. Compare your laboratory established range with the peer group range (ex. Biorad) to ensure you are within the peer group range.	Troubleshooting - Quality Control List some troubleshooting steps for failed QC. • Make sure there is sufficient QC material in the sample cup. • Make sure the correct control product / lot number was used. • Rerun QC using a new sample cup. • Prepare a new vial of QC and rerun. • Run alternate QC or lot number of the same product • Run a patient crossover using both lots of reagent to evaluate possible QC shift due to a matrix effect. • Compare established QC ranges with peer group and adjust as necessary QC deteriorates with age. Check the QC stability after opening the QC vial. Date the QC expiry range to avoid using past expiry date.
QC, Reagent, Hardware failure	Instrument method comparison	A laboratory compares the assay results from a primary instrument with a backup instrument to ensure that if the primary instrument fails, the backup instrument can produce comparable results, guaranteeing accurate patient testing even when switching to the backup device due to a malfunction or maintenance; this comparison is	Perform a QC comparison study with the backup instrument to rule out if the QC out of range is a QC issue, reagent issue or instrument issue. Compare QC using the same lot number to help with troubleshooting.

		crucial for maintaining quality control and patient safety, especially in critical situations where timely results are needed	
Assay Calibration	Note the proper recalibration process for the instrument in question. Example: EXL - Same Flex & same well vs same flex new well vs New flex entirely, what's the appropriate answer? Depends.	The principle of calibrating a Siemens Dimension EXL system involves comparing the instrument's measured values for specific analytes against known standard solutions, allowing for adjustments to be made to ensure the system is producing accurate results within acceptable tolerances, essentially verifying its accuracy by aligning it with a reference standard; this process is typically performed using a series of calibration solutions of varying concentrations and involves the instrument generating a calibration curve to interpret future sample readings.	Pay particular attention to the volume of use of the reagent in question. Low frequency testing can degrade the open well in a flex cartridge. Inspect the reagent carousel for excessive moisture or frost build up. Siemens have studies that show excessive moisture will contaminate an open reagent flex well and will impact accuracy and precision. If the integrity of the reagent flex is in doubt, recalibrate using new QC and reagent.
Over Calibration	Calibration should be performed regularly according to manufacturer guidelines to maintain accuracy and address potential drift in the system. Review the calibration curve for acceptability, checking for linearity and within-run precision If the calibration curve is not within acceptable limits, troubleshoot and adjust the system parameters as needed	You can "over-calibrate" a laboratory Dimension EXL, meaning you can adjust the calibration settings beyond the manufacturer's recommended range, potentially causing inaccurate results by pushing the instrument to measure values outside its designed accuracy limits; however, this is strongly discouraged as it can compromise the reliability and validity of your test results and could lead to serious quality control issues in your laboratory	If the analyzer fails calibration, you need to review the calibration material, instrument hardware. Call hotline for additional troubleshooting.

Precision Study	A precision study is conducted on a laboratory dimension to assess the consistency and repeatability of measurements taken by a specific instrument or technique, ensuring that the results obtained are reliable and not significantly affected by random errors, which is crucial for accurate scientific conclusions in a laboratory setting	Accuracy and precision are evaluated as part of the validation process. The determination of accuracy and precision are often performed concurrently incorporating the same set of data. Example: 1. Perform precision study using preferably 3. Control or calibration material of a different lot number. 2. Example TROP Levels 50, 100, 500 (Low, decision level, and high). Do not select values that would require dilution unless you are intentionally testing dilution precision. Document on appropriate form.	Troubleshooting - Precision Possible causes for failed precision. • Check for missing data points due to processing errors. • Review calibration preparation, storage conditions, and expiration date. • Check that all temperatures are within range • Review maintenance logs and system counter screens for overdue maintenance • Run a 5 replicate precision study Note: To perform a 5 replicate precision study, manually order a sample by using F1: ENTER DATA and select the desired method 5 times.
Accuracy Study	Accuracy determines the systematic error present. It can be verified by using matrix-appropriate reference materials. The materials may be patient samples, altered or unaltered, or other materials with known concentrations	Perform accuracy study, instrument to instrument comparisons spanning an appropriate analytic range spanning the AMR. Document on appropriate form.	To perform an accuracy check on a laboratory dimension, you need to compare the measurements taken by your measuring instrument against a known standard of the same dimension, typically a certified reference material (CRM), and calculate the percent error between the two values, ensuring the deviation falls within an acceptable range based on your laboratory's quality control standards; this usually involves taking

			multiple measurements, calculating the average, and comparing it to the reference value
System Check	A "system check" will verify if the machine is operating within its expected parameters and ready to perform tests accurately; it typically involves running a specific control solution through the system to analyze the results against pre-established standards.	A "system check" on a Siemens Dimension EXL refers to a built-in automated process that runs on the machine to verify the proper functioning of all its critical components, including the sample and reagent fluid metering systems, photometric measuring system, and other key elements.	See System Check Troubleshooting below
Instrument Temperature	A laboratory instrument must operate at a specific temperature because temperature fluctuations can significantly impact the accuracy of the results by altering the properties of samples, affecting the instrument's internal mechanisms, and potentially causing contamination, making it crucial to maintain a controlled environment for reliable patient result.	Ambient temperature range that are out of the instrument performance range can significantly impact accuracy and precision.	Check that all temperatures are within range. The operating temperature range for a Siemens Dimension EXL instrument is typically between 18°C and 30°C (64°F and 86°F). Key points about the Dimension EXL temperature: • **Operating range:** 18-30°C (64-86°F) • **Important to maintain stable temperature:** The room where the instrument is placed should have minimal temperature fluctuations • **Incubation temperature:** The internal reaction area within the instrument is designed to maintain a consistent temperature for assays, usually around 37°C

Sample in instrument	Sample, QC, Calibrator, patient sample sitting in on a clinical analyzer over a prolong period of time can overheat and evaporate.	Samples often contain sensitive and perishable materials that can be easily damaged by changes in temperature. As a result, maintaining stable temperatures is crucial to prevent degradation and ensure that samples are suitable for analysis	When troubleshooting an instrument, always run fresh sample and do not allow sample to sit while waiting for sample aspiration.
Sample Probe	A "sample probe tip" on a Siemens Dimension EXL refers to the small, replaceable tip at the end of the sample probe used to draw liquid samples from a test tube on the chemistry analyzer.	The sample probe tip directly comes into contact with the sample to aspirate it into the system for analysis.	Ensure that the sample probe cleaner is within expiry date. Check probe for damage. If probe integrity is in question, replace and align probe. Perform sample probe ultrasonic testing. Perform a clot check test Inspect sample syringe for drips or leaks.
Reagent Probe	A "reagent probe tip" on a Dimension EXL refers to the small, specialized tip on the automated chemistry analyzer that is used to precisely deliver a measured amount of liquid reagent from the reagent cartridge into the reaction cuvette during a test run.	The reagent probe tip will puncture the reagent flex cartridge to extract the necessary reagent for analysis	Ensure the probe cleaner is within the stability date. Perform a system check to ensure the probe pass. Check for reagent probe integrity. Replace and align. Perform a reagent probe ultrasonics test. Check reagent tubing and connectors for leaks.

Photometer	A "photometer" on a Siemens Dimension EXL refers to the light detection component within the chemistry analyzer that measures the intensity of light absorbed or transmitted by a sample reaction mixture, which is then used to calculate the concentration of the analyte being tested	A photometer is an instrument that measures the strength of electromagnetic radiation in the range from ultraviolet to infrared and including the visible light.	The lamp source degrades over time. A lamp will last about 2000 hours depending on lamp type. Look for QC drift for ALP as it is an indicator of lamp drift and failure. • Perform Photometer Alignment • Clean Cuvette Windows Check Cuvette Film • Replace Source Lamp Replace Optical Filter Replacing the Source Lamp • Raise the thermal chamber. • Check yellow tape to ensure proper closure. • Turn instrument power switch on. • At the console menu, select option 1. Dimension. • Sign in with appropriate Operator ID and password. • Perform a photometer alignment (see alignment procedure on next page). • Perform a system check and daily QC. • Recalibrate the following methods: A1C, C3, C4, CCRP, CRBM, CRP, GENT, HB1C, IGA, IGG, IGM, LIDO, MALB,

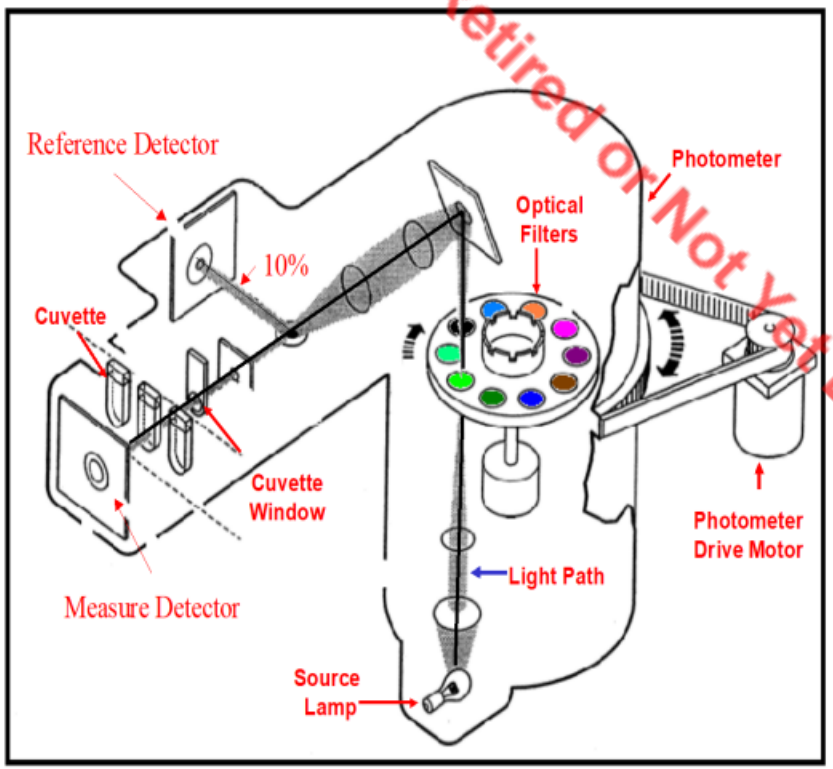
			MPAT, NAPA, PALB, PHNO, PROC, PTN, RCRP, THEO, TOBR, TRNF, VALP, VANC 14. Document in Instrument Log Additional Troubleshooting: Refer to Photometer Module Troubleshooting Table below.
Instrument Maintenance	Instrument maintenance in important to ensure optimal performance and accurate result reporting.	To perform maintenance on a Siemens Dimension EXL system, access the "System Prep" function on the screen, then navigate to "Daily Maintenance" where you can perform routine cleaning and checks, including emptying waste containers and verifying reagent levels; most daily maintenance can be done with minimal hands-on interaction due to automated features on the system.	Perform daily maintenance • Clean sample and reagent probes. • Ensure cuvette ribbon is sealing without leaks. • Empty waste container Perform weekly maintenance • Clean HM wash probe • Reagent R2 probe • Stylet HM wash probes Perform monthly maintenance • Replace HM pump heads. • Clean air filters • Clean reagent drain • Replace IMT pump tubing • Perform clot check • Replace IMT sensor
Cuvette & Window Cleaning	The EXL uses plastic films to form the cuvette	A cuvette on a Siemens Dimension EXL functions as a small, transparent container that holds a sample, allowing a beam of light to pass through it, enabling the machine to measure the sample's absorbance or other optical properties based on the interaction with the light, thereby providing information about the analyte	Ensure that the cuvette sealer is working to prevent compromising the cuvette window. See table below to clean cuvette.

		concentration within the sample; essentially acting as the reaction chamber for the chemical analysis process on the Dimension EXL system	
Di Water	Lab instruments use a deionized (DI) water system because DI water is highly purified, containing minimal ions and contaminants, which ensures accurate and reliable results.	The Dimension uses EXL as part of system operation. It is important to ensure the water supply is not contaminated as it will impact the enzymatic assays.	Check for water resistivity to ensure it meets the manufacturer's specifications. Perform microbial water check as per the manufacturer to prevent instrument contamination. Decontaminating a Dimension EXL will have significant down time.
Hot Line	If all instrument troubleshooting fails, calling the vendor hotline is important. There may be issues the vendor knows can significantly reduce down time.		

System Check Troubleshooting

Failed Module	Resolution
Photometer	Perform Photometer Alignment Clean Cuvette Windows Check Cuvette Film Replace Source Lamp Replace Optical Filter
Reagent R1, R2 or R3 (RMS)	Confirm Correct Carton Value Replace / Align Reagent Probe Investigate Reagent Pump Panel for leaks or crimped tubing Perform Reagent Probe Ultrasonics test
Sampler	Confirm Correct Carton Value R1 or R2 precision or accuracy (resolve R1 or R2 issue first) Replace / Align Sample Probe Investigate Sample Pump Panel Perform Sample Probe Ultrasonics test
HM	Confirm Correct Carton Value R1, R2 or Sampler precision or accuracy (resolve failed Probe issue first) Replace/ align W1 or W2 probes Replace pump cassette or tubing
Sample or Reagent Probe Cleaners	Check Probe Cleaner solution or bottle Check Tubing or connectors for leaks Replace Pump Cassette
LOCI	Reset Statistics Replace/align Transfer arm vacuum cup Replace LOCI insert and rubber seal

Photometric Measurement System



Photometer Diagnostics Screen

F7: Diagnostics > F1: Electro/Mech > F5: Photometer

Acceptable Limits:

Lamp voltage: >6.0 and < 8.0 volts

When troubleshooting with technical support, it may be recommended to replace lamp if voltage reading is below 6.8

Measure frequency: >30,000 and <135,000 Hz (lamp on high) at blank cuvette for all filters except 293

Photometer

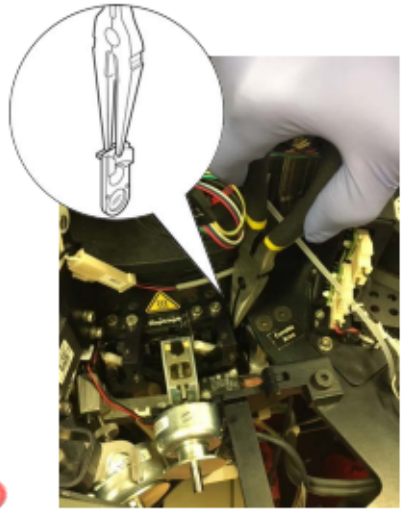
Photometer Module Troubleshooting

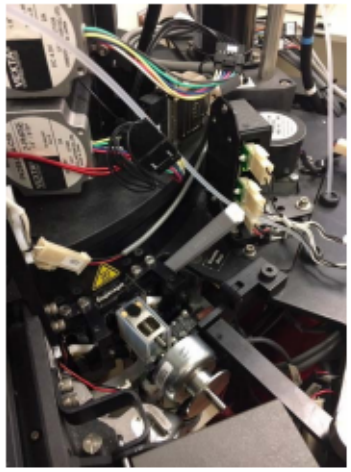
Error Message	Steps to Resolve	Notes
Photometer Source Lamp Problem The computer did not receive a signal that the source lamp was on.	**(278) Photometer Source Lamp Off Detected** Check if LED CR3B on the photometer board is lit and check Photometer Diagnostic screen. If CR3B is out and/or lamp amps <0.1 Amp and lamp voltage >20 Volts: Lamp problem - Perform controlled power shutdown and lower the thermal chamber. - Check that the source lamp connector (P/J 72B) is connected - Replace the source lamp, perform Photometer alignments and all steps in Replacing Source Lamp procedure If lamp voltage is 0, it is not the lamp: - Check the source lamp fuse 24 1D If error message reappears, call CCC-TS. Other probable causes could be a photometer board problem or bad fuse 24 1C	Photometer Diagnostics **F7:DIAGNOSTICS** **F1:ELECTRO/MECH** **F5:PHOTOMETER**
Photometer Mispositioned The photometer did not move the proper distance as verified by the encoder. If the disagreement between the motor and the encoder is 3 to 7 steps, it is considered a fine error. If 8 or more, a gross error.	**Photometer gross (276) and fine (277) positioning error** 1. If the photometer does not move through its complete initialization cycle: Check for interference (film, wiring, and tubing). The most typical cause of this is the photometer hitting bunched up film or the thermal chamber. Perform controlled power shut down, lower the thermal chamber, ensure all cables and tubing are out of the way, and reseat it. 2. If the photometer moves without stopping: - Cycle the photometer - If the Home field does not change to On and then Off during this cycle or if the photometer gets to -11 and makes a loud noise, the sensor has failed. - Change the photometer home sensor. After restoring power perform photometer alignments, System Check and Daily QC 3. If the photometer does not move at all: The fuse may have opened. Check fuse 24 1C on Fuse board A; if not lit, replace the fuse.	**F7:DIAGNOSTICS** **F1:ELECTRO/MECH** **F5:PHOTOMETER** **F8:CYCLE**

Cleaning Cuvette Windows

From the Operating Menu

1. Press **F7: Diagnostics**.
2. Press **F5: Check Windows**.
3. Press **F2: Access Mode** to select access bad or access all.
4. Press **F1: Start Clean**.
5. When prompted, remove the window from the access position (use window extractor tool or needle nose pliers).
6. Clean the window with lens paper and use water if needed.
7. Reinstall the window in the access position.
8. Press any key to continue.
9. Wait for the prompt before removing any additional windows.
10. Repeat steps 5 to 9 until prompted with "All windows have successfully passed QC."
11. Return to the Operating Menu.
12. Select **Reset** to initialize the system.
13. Document in Instrument Log.





Troubleshooting Abnormal Assay

Rerun patient sample along with a QC Sample

Patient sample - abnormal assay QC sample - No error		Patient sample - abnormal assay QC sample - abnormal assay	
Possible Reason	**Investigate**	**Possible Reason**	**Action**
Sample Quality	Are there interferences from exogenous substances?	Reagent	Remove the Flex from inventory and reinstall it. Rerun the patient and QC samples.
Unique sample population	Is the sample pediatric, geriatric, or veterinary?	Maintenance	Align R1, R2 (R3 if RMS) and Sampler. Rerun the patient and QC samples. Clean all drains.
Sample not serum or plasma	Is the sample CSF, synovial fluid, or other non-serum sample?	Water	Perform water supply maintenance. Rerun the patient and QC samples.

3

Addendum B: Monthly QC Review

Monthly QC Review
Overview – What should be included in monthly Technical Supervisor Review • Print LJ Graph (as appropriate), ensure graphs are printed properly, with the current ranges. Denote comments to clarify issues demonstrated on graph: Shifts, trends, and outliers. Verify data is printed against the appropriate ranges. • Maintenance, Temperature/Humidity Logs • QC timing & frequency • Monthly QC Summary Report will capture key elements listed below.
Chemistry • Print BioRad peer data, Lab Comparison Report, evaluate SDI and CVR (as applicable). Understand acceptable performance SDI and CVR </= 2.0. Outliers are reviewed, investigated, and documented. • Print Supervisor Review Report from Unity and retains proof of acceptable action for QC outliers.
Coagulation/ESR/pH (Tests/Data without peer comparisons) • LJ Graphs (Period specific, graphed against our range), verify QC outliers have corrective action • Mean Bar Chart (Period specific), compare SD & mean performance to Cum data. • Print Supervisor Review Report from Unity and retains proof of acceptable action for QC outliers.
Hematology • Sysmex Insight Peer Comparison Data (Review SDI (</=2) and CV (</= 1.5 times peer or cum) • Check for accuracy bias codes. • Review QC for outliers and corrective action.
UN3000/Urinalysis • QC Data and LJ • Review QC to ensure QC frequency (Document misses) • Review QC for outliers and corrective action
Monthly QC Summary Reports (All sections, as appropriate) • Section/Test, Name of QC, Control Lot #'s, Lot Exp Date, Instrument/Device name ID, Lab ID, weekly reviewer initials • QC Lot Changes/Date • QC Range Changes/Date • QC Issues identified, including QC timing & frequency, Corrective Action (Shifts/Trends/Precision/Accuracy) • Correlation/Cross Checks and in-use dates • Instrument issues/Corrective Action/Extended downtimes • Temp/Humidity Issues – document follow, supply impact, patient impact • Testing Suspension/Re-activation (Example: ESR TEMP/QC Out, Temp/Humidity) • Upon reviewing QC, if patient look performed comment used, review patient lookback log for acceptability