Dimension Vista® Systems

Advanced QC Troubleshooting

Virtual Training Workbook

SIEMENS Healthineers

Siemens Healthineers

Dimension Vista® Systems

Advanced QC Troubleshooting Virtual

Training Workbook

Table of Contents

1 Welcome

Welcome to Training

Siemens Healthineers Training would like to welcome you to Dimension Vista Systems Advanced QC Troubleshooting.

This course is designed to clarify QC misconceptions, review quality control & calibration software configurations, and provide resolutions for common issues with QC on the Vista systems.

Our staff welcomes the opportunity to present this virtual training program to you.

Training Material

This training workbook includes an agenda, learning goals and case scenarios.

Course Objectives

Upon completion of the course, you will be able to:

- Describe common misconceptions regarding quality control (QC) practice in clinical chemistry.
- Determine if a QC result is out of range due to an instrument problem or the QC product.
- Identify when to process urine electrolyte QC and to correctly perform an IMT Advanced Clean.
- Configure quality control products, QC ranges and calibration triggers in the Dimension Vista System Advanced software.
- Describe QC matrix and identify actions used to confirm a QC shift due to matrix.
- Schedule patient Lot to Lot Crossover testing.
- Identify resources available for problem solving QC issues in the clinical chemistry laboratory.

Training Agenda

Welcome
Welcome
Quality Control Practices
Case Study One
Case Study Two
Lunch
Quality Control & Calibration Configuration
Case Study Three
Resources
Review and Assessment

Dimension Vista® Systems Advanced QC Troubleshooting Virtual Training

Course Validation Checklist

The student places a checkmark beside the competency when it is completed. When all competencies are checked, the operator will sign and date below as record of completion.

Topics	Competencies	Completed
Quality Control Practices	Identify common misconceptions of QC practice.	
	Describe intended purpose of QC	
Case Study One CTNI Level 2 shifted out of range	Identify the reasons a QC product would cause an out of range QC result	
	Describe where to locate QC product stability information	
	Configure QC stability in the Vista software	
	Discuss how to correctly load QC vials	
	Determine if the instrument or QC product is the cause of an out of range QC result	
Case Study Two Urine Sodium shifted high	Identify when to process urine QC for electrolytes	
	Identify when an IMT Advanced Clean should be performed	
	Discuss the effect of urine QC on the IMT V-LYTE Multisensor	

Topics	Competencies	Completed
Quality Control & Calibration Configuration	Configure QC auto schedule shift times	
	Configure QC products	
	Define and edit QC ranges	
	Configure QC panels	
	Configure QC panel schedule	
	Describe calibration triggers	
	Describe calibration acceptance parameters	
Case Study Three MALB Level 1 shifted low	Describe QC matrix	
	List actions to confirm shift due to QC matrix	
	Describe clinically significant difference	
	Configure lot to lot patient crossover	
Resources	Identify resources available for resolving common QC problems	

Participant:_____

Date: _____

What was most helpful to you during this program?

_____

_____

_____

How can we improve this program to make it more meaningful to you?

_____

_____

_____

2 Quality Control Practices

Quality Control Practices

Objectives

After completing this exercise, you will be able to:

- Identify common misconceptions of quality control practice in clinical chemistry.
- Describe the intended purpose of quality control.

Is that a misconception … or is it reality?

QC Concept	Misconception?	Reality?
The intended use of QC materials is to verify accuracy.		
Running more controls improves method performance.		
If QC is out of range recalibration is a good way to solve the problem.		
QC samples react the same as patient samples.		
Using 2 SD limits is the best practice.		

QC Concept	Misconception?	Reality?
Peer group data verifies accuracy of results.		
Package insert or peer group values should be used for target mean and SD to assure accuracy.		
It is not acceptable to be biased high or low within my peer group's range.		
Tightening QC target ranges improves method performance.		
Target mean and SD should never be changed.		

3 Case Study One

Case Study One

Objectives

After completing this exercise, you will be able to:

- Identify the reasons a QC product would cause an out of range QC result
- Describe where to locate QC product stability information
- Configure quality control stability in the Vista software
- Discuss how to correctly load quality control products into the Vista
- Determine if the instrument or QC product is the cause of an out of range QC result

Case Study One

Scenario:

CTNI Level 2 QC shifted out of target range

There is a red alert for CTNI QC out of range on instrument #1.
You click on the alert and note that Level 2 has shifted out of range while Level 1 is well within range.

Level 2 QC target range: 0.680 – 0.960 ng/mL

Date/Time	Concentration	Reagent Lot #
12-10 09:56	0.678 ng/mL	14251BC
12-10 08:13	0.677 ng/mL	14251BC
12-09 08:55	0.665 ng/mL	14251BC
12-09 08:12	0.668 ng/mL	14251BC
12-08 07:46	0.694 ng/mL	14251BC
12-07 08:31	0.705 ng/mL	14251BC
12-06 09:30	0.711 ng/mL	14251BC
12-05 09:30	0.712 ng/mL	14251BC
12-04 08:42	0.723 ng/mL	14251BC

- You check instrument #2 and note CTNI QC Level 1 and Level 2 are both within target range. No problems on instrument #2.
- You check the reagent lot numbers used and take note they are all the same.
- A new bottle of level 2 QC was loaded on instrument #1 and the control was repeated. This didn't solve the problem.
- You decide to unload the QC vial from instrument #1 and run it in a cup on instrument #2. The QC recovers 0.665.

What are the possible reasons for the out of control QC results?

What is the resolution?

Is the out of range QC result due to the analyzer or the QC product?

1. Remove the vial in use and inspect it.
2. If there is enough fluid in the vial, place the contents of the vial in a cup and process on another Vista as a patient sample.
3. If the results are clinically similar the issue is most likely the control product in the vial. Process QC using fresh product.
4. If the results differ, then the issue is most likely a system problem.

Possible causes for the QC product as the source of the out of range result?

- Wrong QC product is in the vial.
- The vial was overfilled and the QC product has dried onto the cap.
- The vial was under filled and has run dry.
- The QC product was not handled according to manufacturer's instruction.
- The QC product was not loaded immediately after preparation was complete.
- The QC product was not configured properly in the Vista software.
- QC product was not handled per manufacturer's IFU recommendations for:
    - Storage
    - Stability
    - Preparation for use

Loading QC Vials

- Siemens and other QC manufacturers supply QC vials with preprinted barcode labels that are filled and ready to be loaded on the system.
- For QC products without barcode labels, the operator must use the empty vials supplied by Siemens after applying a barcode label. Vials must be filled with the volume configured in the QC Product setup procedure.
- The default volume on the QC product setup screen is 2000 µL. Do not exceed 2500 µL of QC material in the vial.

- On the QC vial inventory screen, the dead volume (200 µL) is accounted for in displaying the volume available for processing.

4 Case Study Two

Case Study Two

Objectives

After completing this exercise, you will be able to:

- Identify when to process urine QC for electrolytes.
- Identify when an IMT Advanced Clean should be performed.
- Discuss the impact of urine QC on the V-LYTE Multisensor.

Case Study Two

Scenario

As you return from break you are told by a co-worker that both Level 1 and Level 2 of the Urine Electrolyte controls are out of range and are high.

This has been an ongoing issue in your lab. The chemistry tech has run controls a total of 10 times today in an attempt to obtain results within range.

V-LYTE Multisensor lot 4KD072 is currently in use but the same issue has occurred with other lot numbers.

Only four patient serum samples had been processed on the Multisensor prior to processing QC.

You are aware that earlier this week the IMT Probe was aligned by a tech on the night shift.

Today's Urine NA QC results

Level 1 QC = 95 98 98 mmol/L	QC target range = 76-88 mmol/L
Level 3 QC = 186 187 190 mmol/L	QC target range = 151-171 mmol/L

Peer data:

Level 1 mean (sd) = 81.3 (1.4)	3SD range (77-86) mmol/L
Level 2 mean (sd) = 165.5 (3.3)	3SD range (155-175) mmol/L

What are the possible reasons for the out of control QC results?

What is the resolution?

Recommendations to optimize urine NA QC performance

- Avoid running urine QC when the system is in an under-conditioned state due to long periods of standby or immediately after Routine Clean during Off-Peak Activities.
- Configure urine QC to process after the system has been protein conditioned by a large volume of serum/plasma samples.
- Perform advanced clean when prompted. Refer to the Maintenance section of the Operator's Guide (10807656 Rev.A 2017-3 page 7-27).
- If the laboratory receives a low volume of requests for urine LYTES, consider a separate urine LYTES QC panel configured to run "As Needed" when a request for urine LYTES is received.
- The typical SD for urine sodium QC performance is not the same as serum QC performance. Ensure urine NA QC ranges are consistent with QC peer data and not similar to serum QC ranges to avoid a high frequency of false rejections of good urine QC runs.
- Avoid processing multiple runs of Urine QC material. The preservatives and stabilizers contained in urine QC are unfavorable to the long term stability of the IMT sensor.

5 Quality Control & Calibration Configuration

Quality Control Configuration

Objectives

After completing this exercise, you will be able to:

- Configure QC auto schedule shift times.
- Configure QC products.
- Define and edit QC ranges.
- Configure QC panels.
- Configure panel schedule.
- Describe calibration triggers.
- Describe calibration acceptance parameters.

Use the following to Configure QC Shift Times

1. Navigate to **Advanced > Configuration > QC Configuration**
2. Select **Modify QC** from the Action menu.
3. Check the boxes next to **Shift 1** and **Shift 2**. For each selected shift box enter a time of day that QC processing should begin. Example: 08:00:00, 16:00:00.
4. Enter a number in the Interval between times when QC is required field. If QC is not run for the method during the interval specified (24 hours is recommended) the system will run QC automatically.
5. For QC Alerts to appear you must check the box next to “Display alert on QC Out of Range”.
6. Select **Save Changes.**

Use the following to Configure QC Product

1. Navigate to **Advanced > QC > QC Product Setup** screen.
2. View **Product Details** from Actions menu on the left task bar
    - The top half of the screen lists all the products.
    - The individual lot details and method ranges of the selected product are displayed in the bottom pane. This provides an overview of the QC products set up for use.

3. Navigate to **Edit Product**
    - **Manufacturer:**
    - **Product Name:**
    - **Fluid Type:**
    - **Lot Type:**
    - **On Board Stability: X Days**
    - **Open Vial Stability: X Days, refer to QC Product IFU**
    - Fill Volume (ul): 2000ul (default 2000ul)
    - Type: **Unassayed, Assayed**
    - Number of levels, Lot Number
    - Expiration, Sample ID
    - Catalog number, Methods (for instance: NA K CL BUN CRE2 GLU CA C02)

4. Select: **Save Changes**

QC Panel Set-up

QC panels are sets of tests that are ordered together from a common control product.

A QC panel contains a unique panel name, a list of methods and, optionally, a schedule to run QC automatically.

When a control product is first created a default QC panel is created that contains all the methods in the product.

Any method can be in more than 1 panel.

Use the following to Configure QC Panel

1. Navigate to **Advanced> QC> QC Product Set-up**
2. In View menu select **Panels**
3. In the bottom half of the screen under Actions select **Create New Panel.**
4. Enter panel name and select tests.
5. Select **Save Changes**.

QC Panel Schedule

Schedule from the following options:

- **Number of Samples:** QC is processed automatically after the specified number of samples has been processed.
- **Time of Day (Daily)**: QC is processed based on the time/shift specified on the QC Configuration screen.
- **Time of Day/Weekend Off**: Time of day/Weekend Off only runs Monday-Friday, no weekends.
- **Not Auto Scheduled**: No automatic QC processing. “QC Needs to run” alert is displayed.
- **As Needed**: QC is processed only when a patient test is ordered for which QC has not been processed in the time entered in the **Interval between times when QC is required** field on the QC Configuration screen.

Use the following to Configure Panel Schedule

1. Navigate to **Advanced > QC> QC Panel and Results > Panel Schedule**
2. **Highlight Control Panel to be scheduled**
3. Select **Edit Schedule** in the Action menu.
4. Select **Time of day:** to display shift times and levels to be run.
5. To specify that the control product will be used with calibration select the check box **Use with Calibration**.
6. If the QC Source is Vials, **Use with Calibration** is checked by default in the software.
7. Select **Save Changes**

Use the following to Edit QC Ranges

To edit QC ranges, enter min/max values for the methods, highlight the product name in the top half of the screen. In the bottom half of the screen, select Edit Level from the Edit Ranges sidebar menu.

1. Select **Advanced > QC > QC Product Setup** from the menu.
2. Highlight the QC product you want to edit by clicking on it.
3. Select **Product Details** from the sidebar menu.
4. Select desired level (1,2,3) from the drop-down menu and **Select Edit Level**.

CHEMTRAK QC		
Method	Level 1	Level 2
BUN	14-17	36-44
CA	7.2 – 8.2	12.0 – 12.8
CHOL	200 – 220	140 -158

Let's review how QC is configured to process with calibrations …

Configure Calibration Triggers

Triggers are used to initiate automatic calibration. Any or all of the following can be configured:

- Expiration – select the time frame within which calibration should take place
- New Lot – when a new lot of reagent is loaded onto the Vista
- IFU Changed – Calibrator IFU bottle values are modified

To specify calibration triggers:

1. Select **Advanced > Configuration > Method Configuration**.
2. Select a method from the sidebar list.
3. Select **Modify Method** from the Actions menu.
4. Select **Triggers** on the Calibration box.
5. Select **Auto Trigger**. Then select desired parameters.
6. Select **Save Changes** from the Actions Menu.

Run QC with Calibration

Use this feature to specify that QC is run immediately after a calibration.

To configure QC to run with calibration:

7. Select **QC** on the Calibration box.
8. Select the parameter **Run QC with Calibration**.
9. Select **Save Changes** from the Actions Menu.

Configure Calibration Acceptance

Use this feature to specify the parameters for calibration acceptance. When configured a yellow alert notifies the operator when a calibration has not auto-accepted and requires review.

To configure Calibration Acceptance Parameters:

1. Select **Acceptance** on the Calibration box.
2. Verify **Automatic Acceptance** is selected.
3. The following acceptance criteria are set in the software:
    - Percent Bias
    - Slope Range
    - Intercept Range
    - Percent Deviation
    - Percent Deviation, Except low
4. Select **QC results must be within ranges** if desired in your laboratory.
5. Select **Save Changes** from the Actions Menu.

6 Case Study Three

Case Study Three

Objectives

After completing this exercise, you will be able to:

- Describe QC matrix.
- List actions to confirm shift due to QC matrix.
- Define clinically significant difference.
- Configure lot to lot crossover testing.

Case Study Three

Scenario

You obtain a QC out of range alert for MALB Level 1 QC. You click on the alert and note the following:

Level 1 QC Target Range = 6.8-10.6 mg/dL

Date/Time	Concentration	Reagent Lot #
05-16 12:17	6.47 mg/dL	16260MA
05-16 08:40	9.10 mg/dL	16134MA
05-15 08:49	8.87 mg/dL	16134MA
05-14 14:37	6.63 mg/dL	16260MA
05-14 14:12	6.32 mg/dL	16260MA
05-14 13:49	6.58 mg/dL	16260MA
05-14 13:11	6.54 mg/dL	16260MA
05-14 11:54	6.53 mg/dL	16260MA
05-14 11:21	6.49 mg/dL	16260MA

Level 2 QC Target Range = 9.7-14.9 mg/dL

Date/Time	Concentration	Reagent Lot #
05-16 12:24	11.0 mg/dL	16260MA
05-16 08:40	12.6 mg/dL	16134MA
05-15 08:45	12.7 mg/dL	16134MA
05-14 14:38	10.8 mg/dL	16260MA
05-14 14:13	10.6 mg/dL	16260MA
05-14 13:49	10.6 mg/dL	16260MA
05-14 13:18	9.84 mg/dL	16260MA
05-14 11:49	10.7 mg/dL	16260MA
05-14 11:47	10.6 mg/dL	16260MA

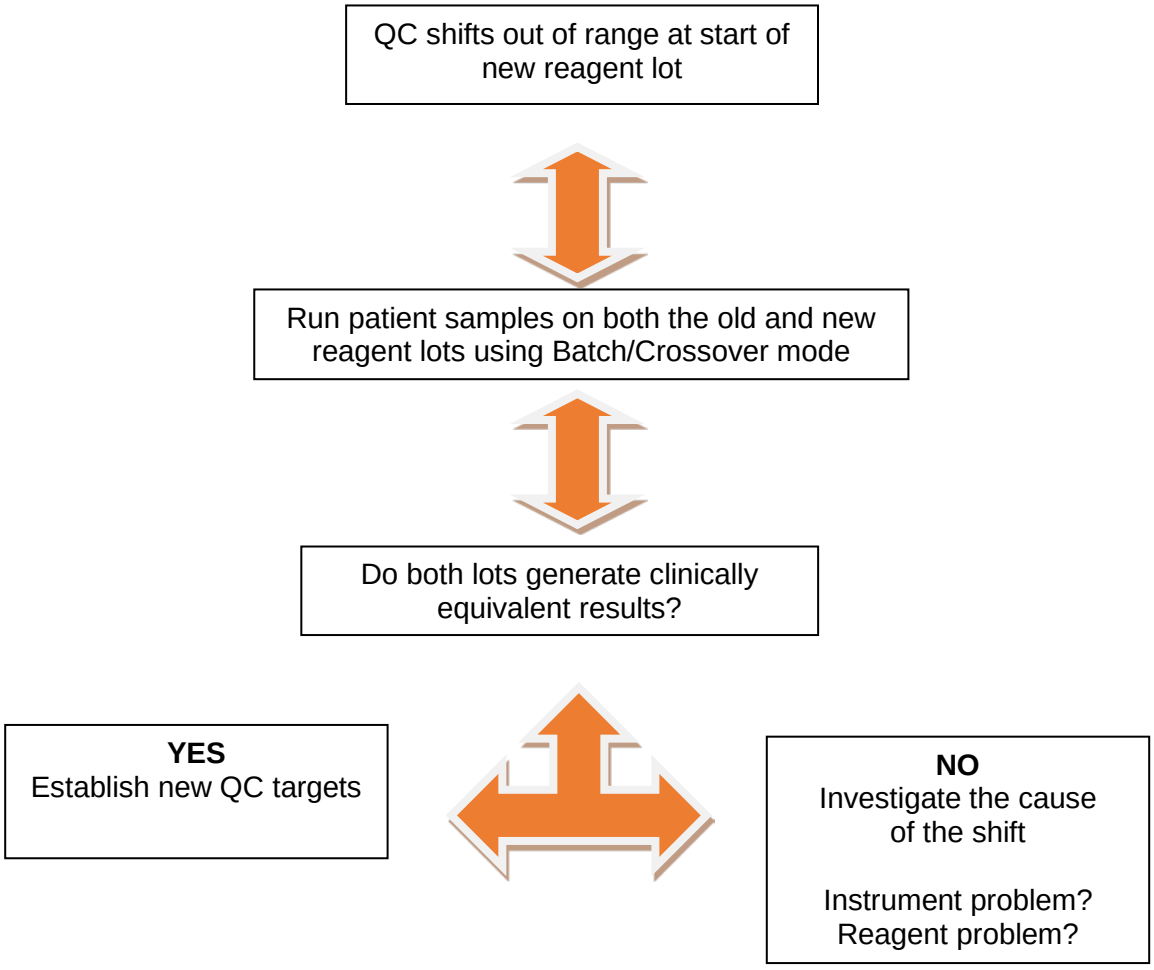
What are the possible reasons for the out of control QC results?

What is the resolution?

QC Matrix

- Quality control products are not identical to patient samples. They are pooled samples with added analytes, additives and preservatives. The matrix is all of the components of a control product *except* the analyte.
- Some assays are more sensitive to the matrix of the QC product; especially immunoassays and enzyme activity assays.
- A new reagent can exhibit a shift in the quality control results but patient results show no clinically significant difference.

Verifying Reagents lot to lot – Verifying quality results



Lot to Lot Patient Crossovers?

Note: If you want a printout of results check system configuration setting prior to processing the batch.

1. Select **Advanced** >**Samples.** Select **Batch Test Mode Test Setup** from the menu.

2. Select **Create Batch Mode Configuration** or **Modify Batch Mode Configuration** from the Actions menu. *Note: if configured in the past for batch mode analysis "Create Batch Mode Configuration" will be replaced by "Delete Batch Mode Configuration."*

3. Enter Batch ID in the Batch ID field. For example: "CTNI 1701BB 1207BA"

4. Select "Sample Fluid Type" from the drop-down menu.

5. Select the method(s) to be processed. If multiple replicates are needed, select the method of choice and the number of times needed to be run.

6. Scan the sample rack barcode. The barcodes are listed in the display box. The sample rack barcodes can also be manually entered in the space provided. (Rack barcode example: AL000566)

7. Press **Save Changes** in the Actions menu.

8. Select **Lot Crossover** in the Batch Mode menu.

9. Load the sample racks on the instrument.

10. When the batch mode is processed the sample ID is generated by Rack-Position+Sequence number. The same sequence number is added to the Batch ID to form the Patient ID field.

11. As the results are completed, the Dimension Vista® System displays the results on the Results History screen. The results can also be viewed in the Test Status screen.

Note: Once all of the samples in the racks designated to process the Reagent Crossover have completed, those sample racks used in the study automatically process as normal sample racks for subsequent patient orders.

Determining if results are significantly different or similar …

- **Clinical significance** is the practical importance of a diagnostic result, whether the difference has a real genuine, noticeable impact.
- Results can be statistically different but not clinically different
- Clinical difference will not be the same for every method.
- “Less than 10%” will not work for all methods.
- Must take into account method imprecision.
- Possible ways to determine clinically significant difference:
  - Clinical outcomes
  - Medical or professional recommendations

7 Resources

Resources

Objectives

After completing this exercise, you will be able to identify resources available for further education.

Additional Resources

Method IFU includes information about:

- Expected method precision
- Analytical sensitivity
- Limits of detection
- Reference Ranges

PEP Connect (www.siemens.com/pepconnect)

- Common Reasons for Out of Range QC Results by Nils B Person PhD
- Managing Reagent Lot to Lot Changes by Nils B Person PhD

Publications

- *Statistical Quality Control or Quantitative Measurement Procedures: Principles and Definitions* 4th ed. CLSI guideline C24. Wayne, PA: Clinical and Laboratory Standards Institute; 2016
- Westgard, JO Basic QC Practices, 3rd Ed., Westgard Quality Corporation, 2010
- Brooks, ZC, Performance Driven Quality Control, AACC Press, 2001
- Wheeler, D and Chambers, D, Understanding Statistical Process Control, 2nd Ed. SPC Press, 1992