QC BIORAD UNITY REAL TIME

☒ St. Joseph Medical Center, Tacoma, WA	☒ St. Anthony Hospital Gig Harbor, WA	☐ Harrison Medical Center, Bremerton, WA
☒ St. Francis Hospital, Federal Way, WA	☒ St. Elizabeth Hospital Enumclaw, WA	☐ Harrison Medical Center, Silverdale, WA
☒ St. Clare Hospital Lakewood, WA	☒ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

Control procedures are performed to monitor the stability of the method or test system and to assure the accuracy and reliability of patient test results. The purpose of this policy is to maintain a standard protocol for documenting the review of QC data.

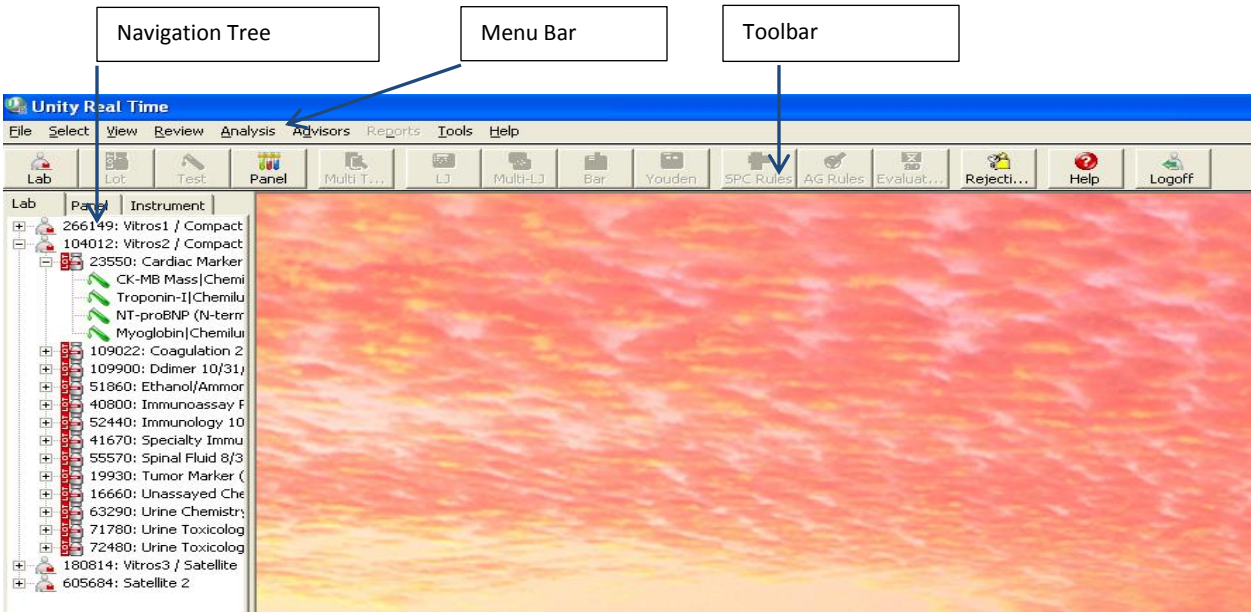
PROCEDURE

Log into Unity Real Time Application

1. Double click on the application shortcut on the computer desktop.
2. Select your user ID from the dropdown box in the User field and enter password.
3. Click OK or press enter

Unity Organization/Layout

QC data is stored and organized in the Unity software and can be viewed using the navigation tree found on the left hand side of the program. The Unity program uses a hierarchical structure of lab number, lot number, and test codes to uniquely identify each test in the laboratory.



Lab numbers are a unique set of 6 digits that are assigned to the lab by BioRad.

BioRad and non-BioRad QC lots can be used in the Unity program; however interlaboratory reports are only available for BioRad products.

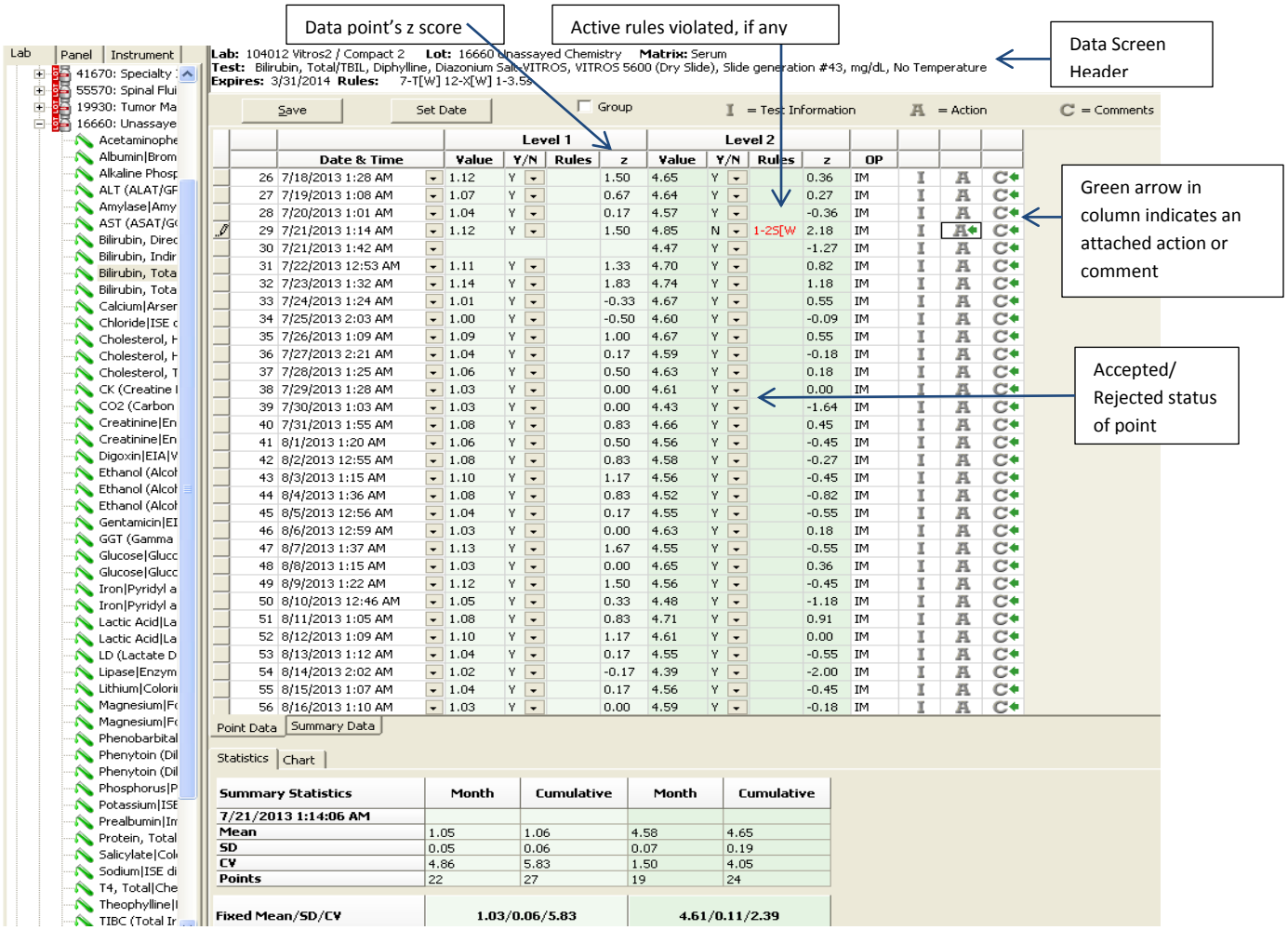
Tests are defined using 6 parameters: Analyte, Instrument, Reagent Type, Method, Unit of Measure, and Temperature.

Items in the tree can be collapsed or expanded. Collapsed items are indicated by a plus sign (+). Expanded items are indicated by a minus sign (-). Click a collapsed item to expand it.

Menu and Toolbar items become available or unavailable depending on which item (lab, lot, or test) is selected in the tree. For example, charts and reports are available only when a test is selected in the tree.

Data Entry Overview

Double click on test in the navigation tree to view the point/summary data screen for the selected assay.



The header for each data screen provides description including lab number and lab description, lot number with matrix and expiration date, Unity codes used to define test, and list of active Westgard rules for analyte.

z score: Indicates the number of SDs the data point is from the evaluation (expected) mean

$$z\text{-score} = \frac{\text{Observed Result} - \text{Expected Mean}}{\text{Expected Standard Deviation}}$$

Accepted/Rejected Status (Y/N): Indicates whether the data point was accepted (Y) or rejected (N). Unity will automatically reject any data row that contains a point that violates a rejection rule.

Actions are pre-defined messages that allow standardization of actions to correct a QC error situation.

Free text Comments are intended to document unusual occurrences or to further explain actions as needed.

Pre-Coded actions and free text comments allow for the addition of information to any data row. Used together, actions and comments provide the means to document changes in the test system and actions taken to correct those changes.

REVIEWING AND COMMENTING ON QC DATA

Regulatory agencies require that review of QC data is documented. Bench review and Supervisor Review automates this review and allows QC data to be sent to BioRad for inclusion in Instant QC reports.

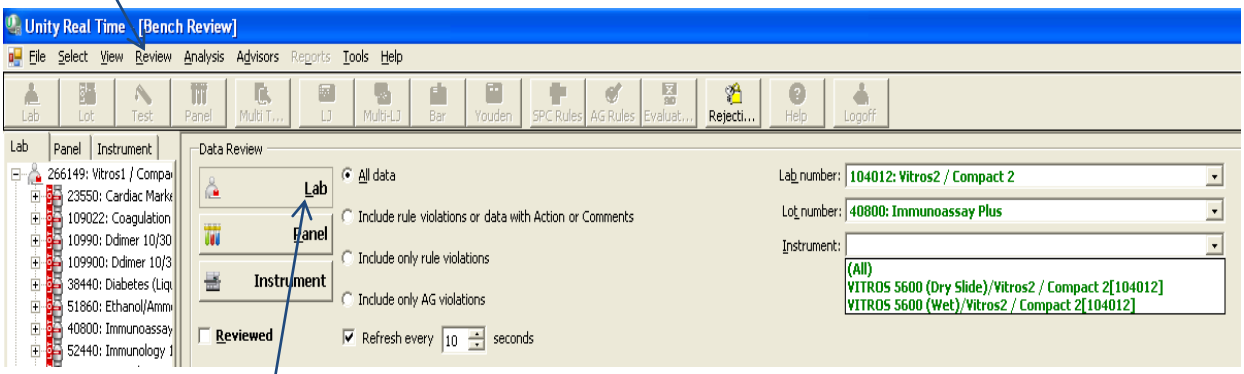
Performing Bench Review

Bench Review allows the laboratorian performing testing to review QC results before verifying patient results.

Selecting Data Set

a. On the Menu bar, click the **Review** tab and then click **Bench Review** from the dropdown list or click on the Bench Review icon in the toolbar.

b. When Bench review is opened, the default review modes on the left hand side of the screen are Lab and “all data”. Do not change to any other review mode.



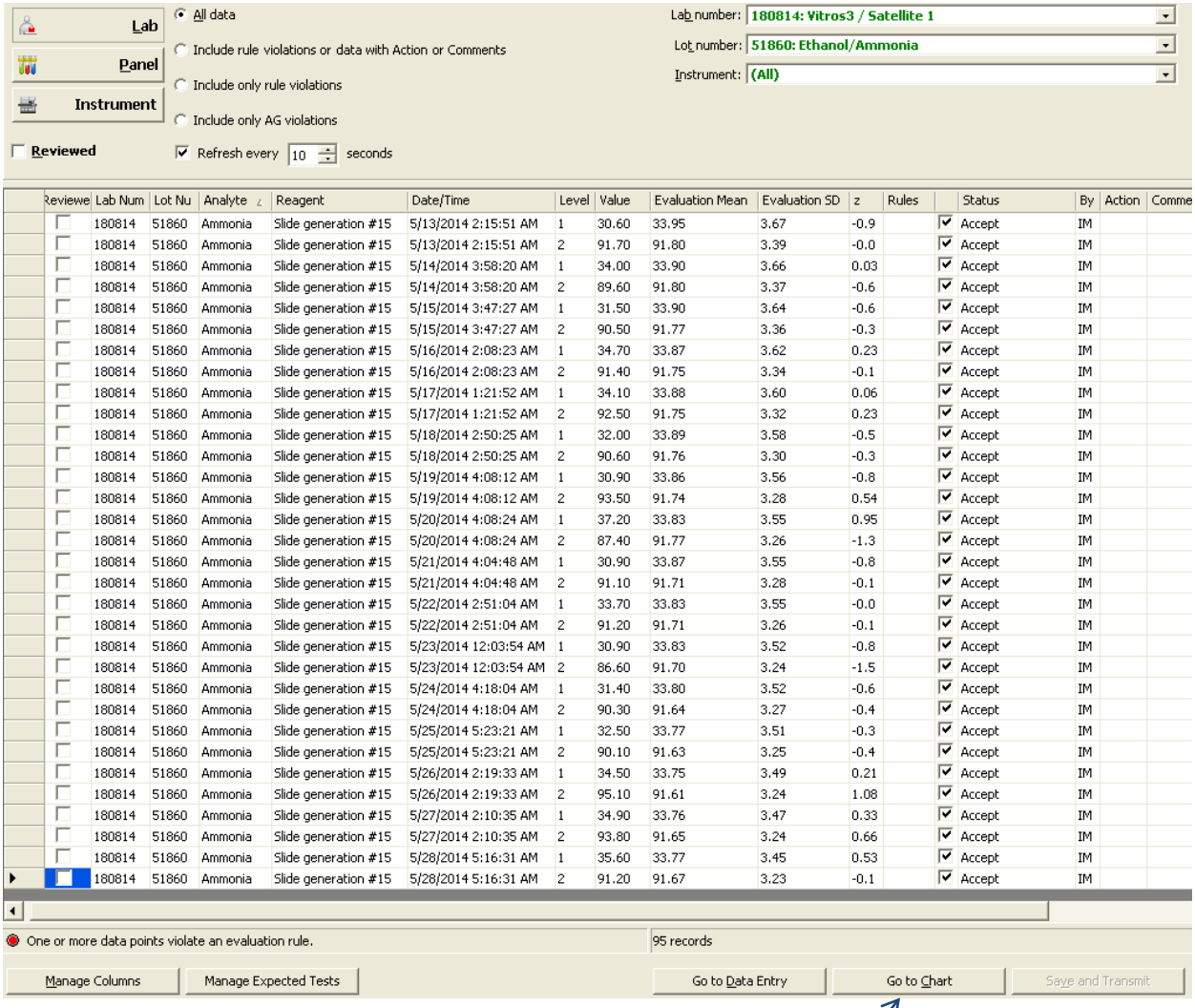
Default review mode is Lab and “All data”

c. Select the **Lab Number, Lot Number & Instrument** from the dropdown boxes on the right side of the screen to view QC data. Any lab number, lot number, or instrument in the dropdown lists that are green indicate that there is data to be reviewed.

Reviewing Data

After a data set has been selected, Unity will display each data point within the selected set. The review screen contains information including the QC value, its evaluation mean and SD, and any attached actions or comments. In addition the "**Go To Chart**" button can be used to branch to the Levey-Jennings chart of a selected assay to review suspect QC data or as a supplement to the Bench Review grid.

Bench Review data displays in chronological order. Data can be put in order of Analyte by clicking on that column header. During the review, you may also wish to disable the "Refresh" function in order to keep your place during a long review. You can disable the Refresh by unchecking that box in the header.

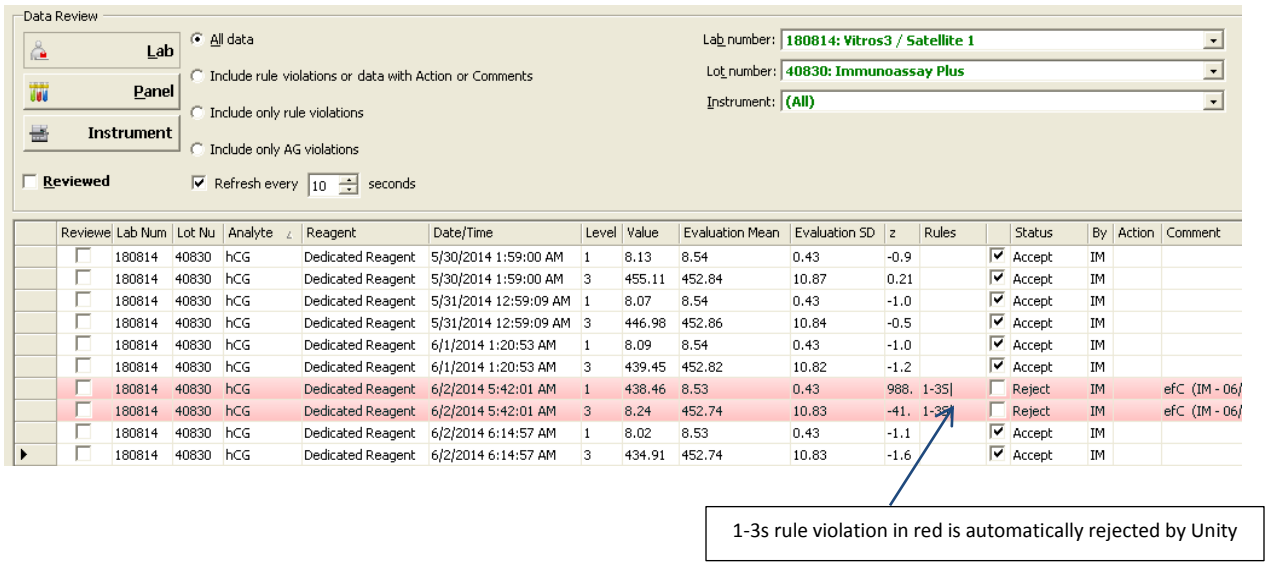


Go to Chart branches to Levey-Jennings chart for review

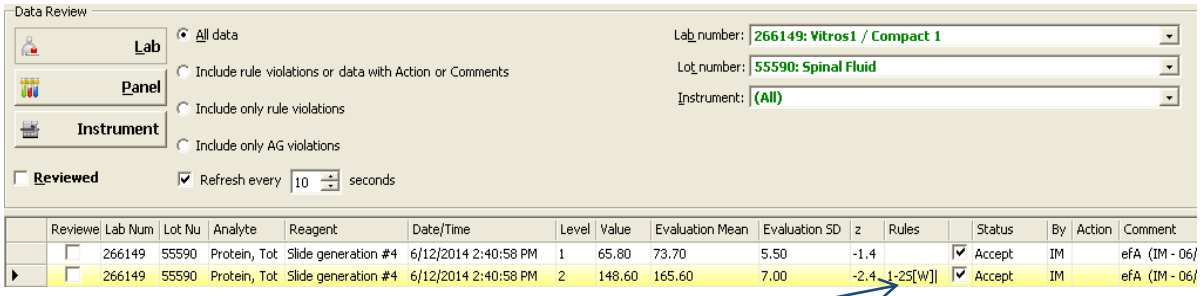
When a data point violates a rejection rule:

- Data points that violate a reject rule are highlighted in light red and data points that violate a warning rule are highlighted in yellow. Data that violates a qualitative tests' "expected response" will be highlighted in orange.

- The Status column will display “Reject” and the checkbox just to the left of the status column will be unchecked. If a data point violates a reject rule, but is actually an acceptable value (ex. new lot reagent and QC out less than 3sd), you may change the status of the data point to “Accept” and document the reason for acceptance using the pre-defined action code “Reagent:new lot”.
- The violated rule appears in the Rules column
- The accept and rejection of rule violations in Unity is by QC run rather than by level; therefore any data point within a run that contains a rule violation will be rejected by Unity. Unaffected data points can be manually changed from Reject to Accept.



1-3s rule violation in red is automatically rejected by Unity



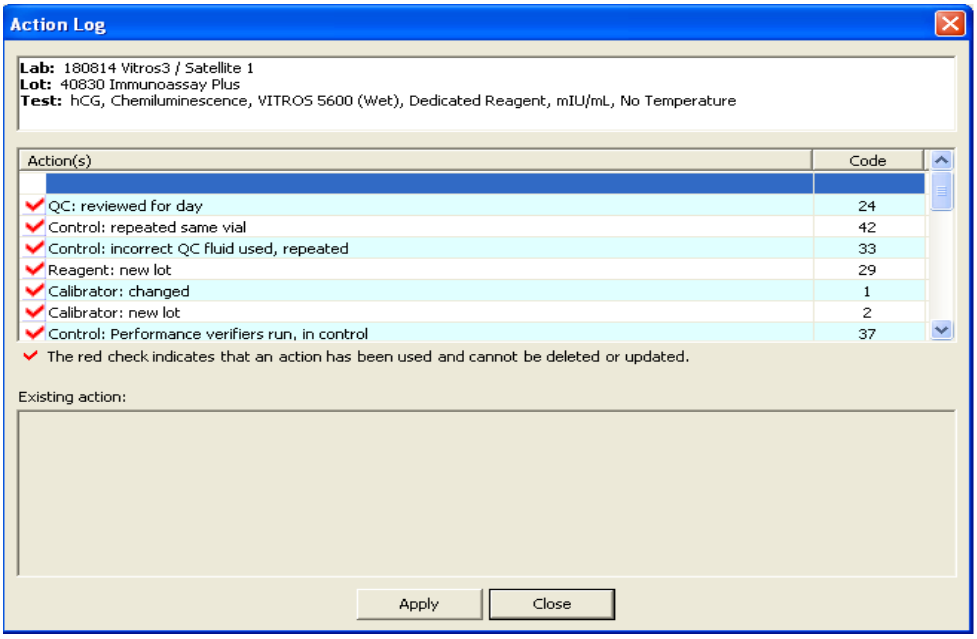
Rule warnings (such as 1-2s) in yellow are automatically accepted

Adding an Action or Comment

The pre-defined set of actions that appear in the action log are intended to standardize documentation of events that occur repeatedly.

<u>To enter an action for a specific data point entry:</u>

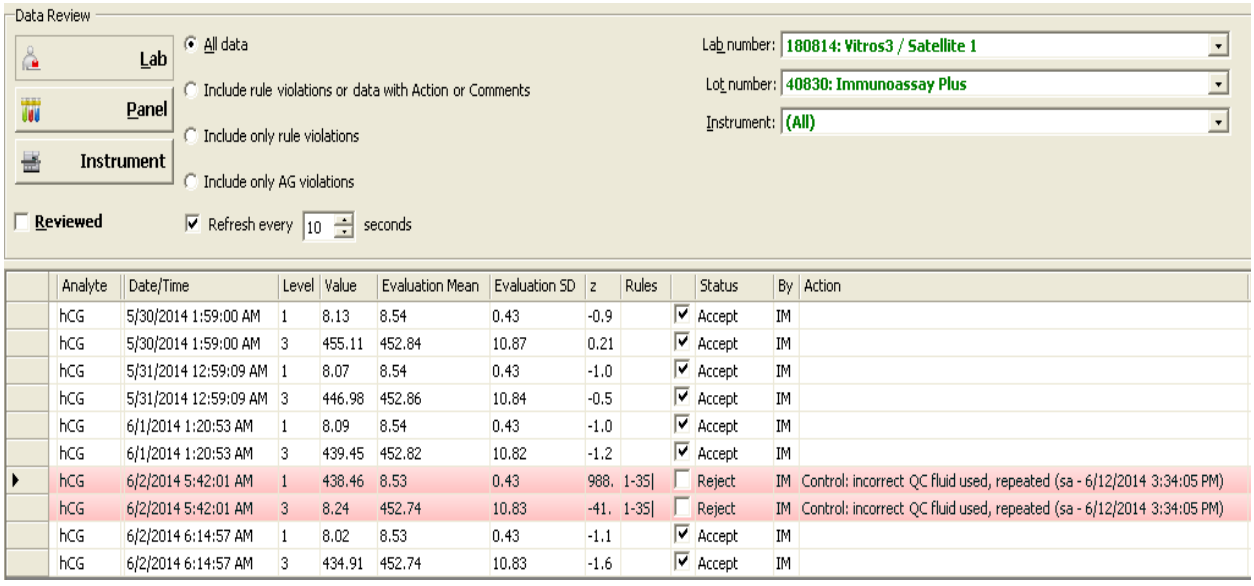
1. Click in the Action column of the row where you want to add the action. A message box appears with a list of pre-defined actions



2. Select an action from the list and click Apply. The selection will be added to the "existing actions" portion of the dialog box.

3. Click close to exit or to append another action.

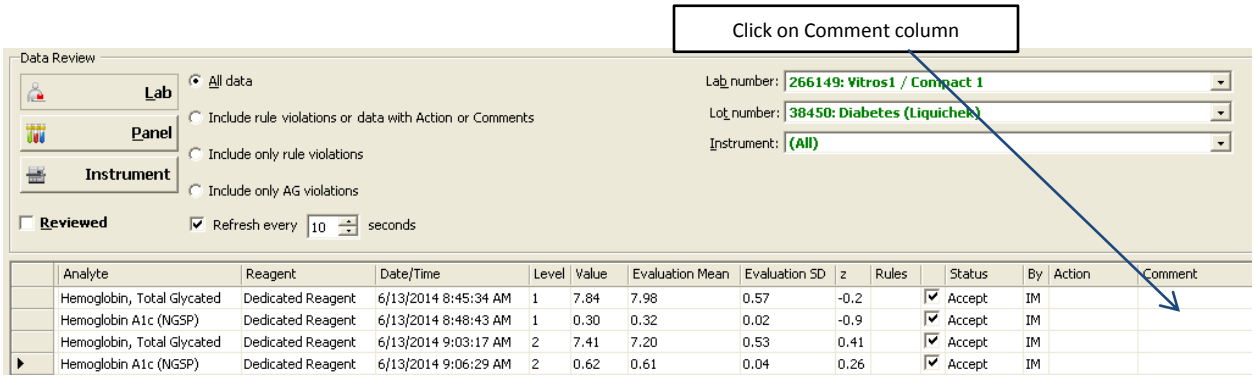
4. The selected actions now appear in the "Action" column along with tech initials and date and time.



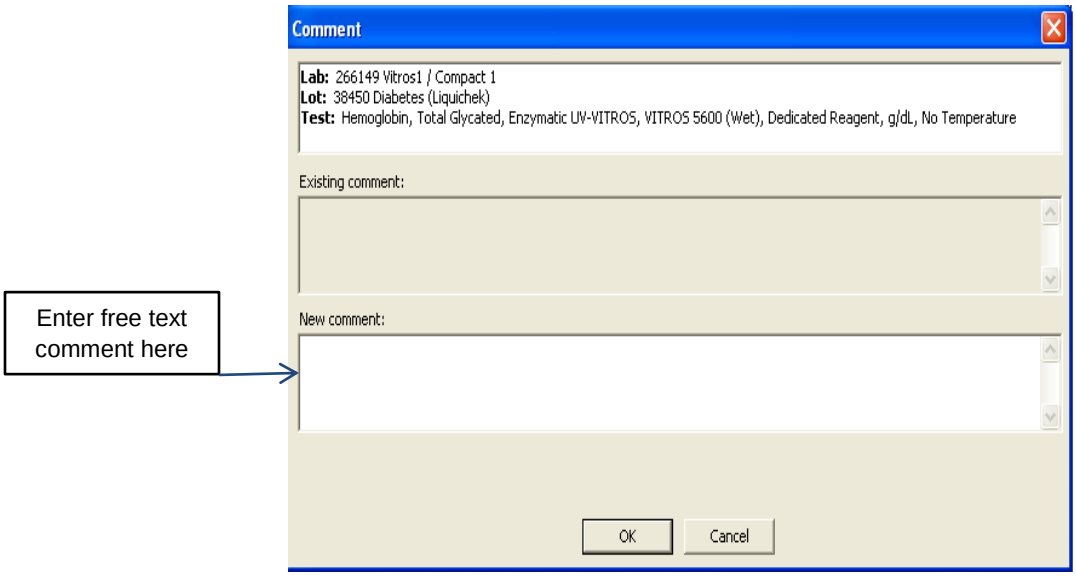
Note: Once an action has been added it cannot be deleted. If you have chosen the wrong Action, please add another more appropriate Action, if available, and/or use a Comment to correctly describe the situation.

To enter a comment:

1. Click on the Comment column for the QC data



2. Type the comment in the New Comment field and click OK



This should only be done if enough documentation cannot be provided from the action step.

Viewing a Levey-Jennings Chart from the Bench Review

1. It is possible to view a Levey-Jennings Chart while in the Bench Review screen to review suspect QC data or as a supplement to the Bench Review grid. From the Bench Review grid, click **Go to Chart**.

2. Levey-Jennings for the last two months of data will appear. To review a different date range, adjust the date range in using the tab in the upper left corner of the screen.

3. Investigate the suspect QC data. Position the mouse over the suspect QC data point to view the details.

4. Click ☒ located in the upper right hand corner to close the Levey-Jennings Chart and return to the Bench Review.

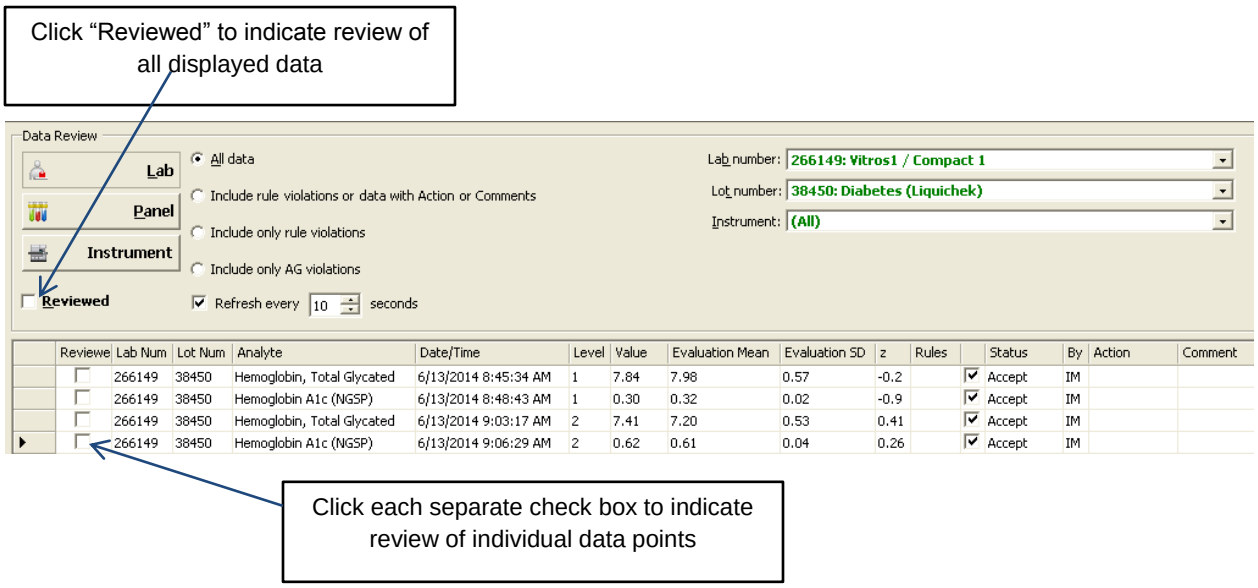
Documenting Bench Review

To indicate review and acceptance of the QC data:

1. Select the **Reviewed** check box to indicate review of <u>all</u> QC data points

   Or

   Click the “Reviewed” check box to the left of a test to indicate review of the point and any other data points for the assay that were run at the same time. For example, if you click the “Reviewed” check box for a level 1 value, the level 2 value will also be selected if both levels were run at the same time.



2. Click **Save or Save & Transmit**

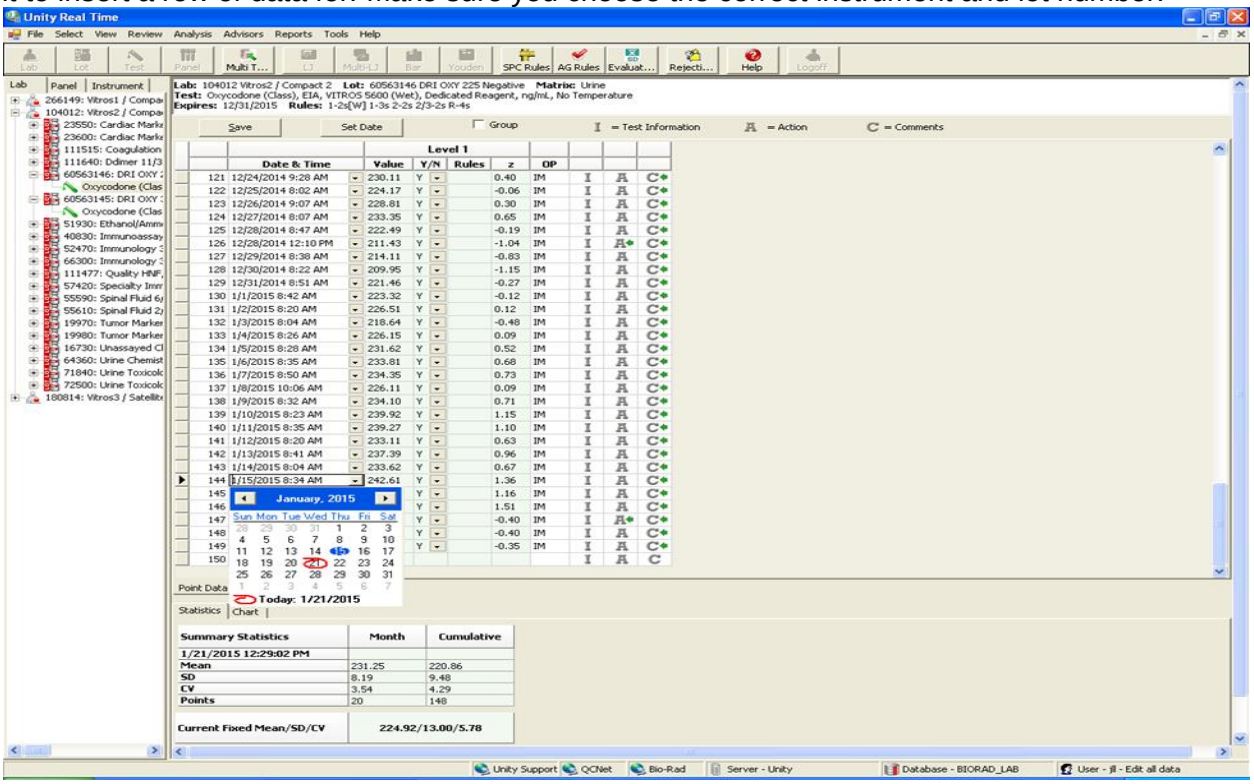
3. Once the data has been reviewed and saved it will be cleared from the screen. Each shift must review all QC data. QC should not be left un-reviewed from a prior shift.

MANUALLY ENTERING DATA

Manually Insert a Data Row (if needed)

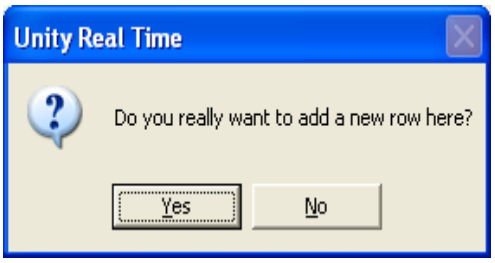
Note: A data row *may* need to be manually inserted when entering data for a **previous** date or time**.**

1. To manually insert a data row, double-click the test in the Lab, Panel, or Instrument navigation tree you want to insert a row of data for. Make sure you choose the correct instrument and lot number.



2. Select the row you want to use to insert data a row above.
   Tip: the row is inserted above the line you select.

3. Press the INSERT key on the keyboard. This box will appear after pressing the INSERT key.

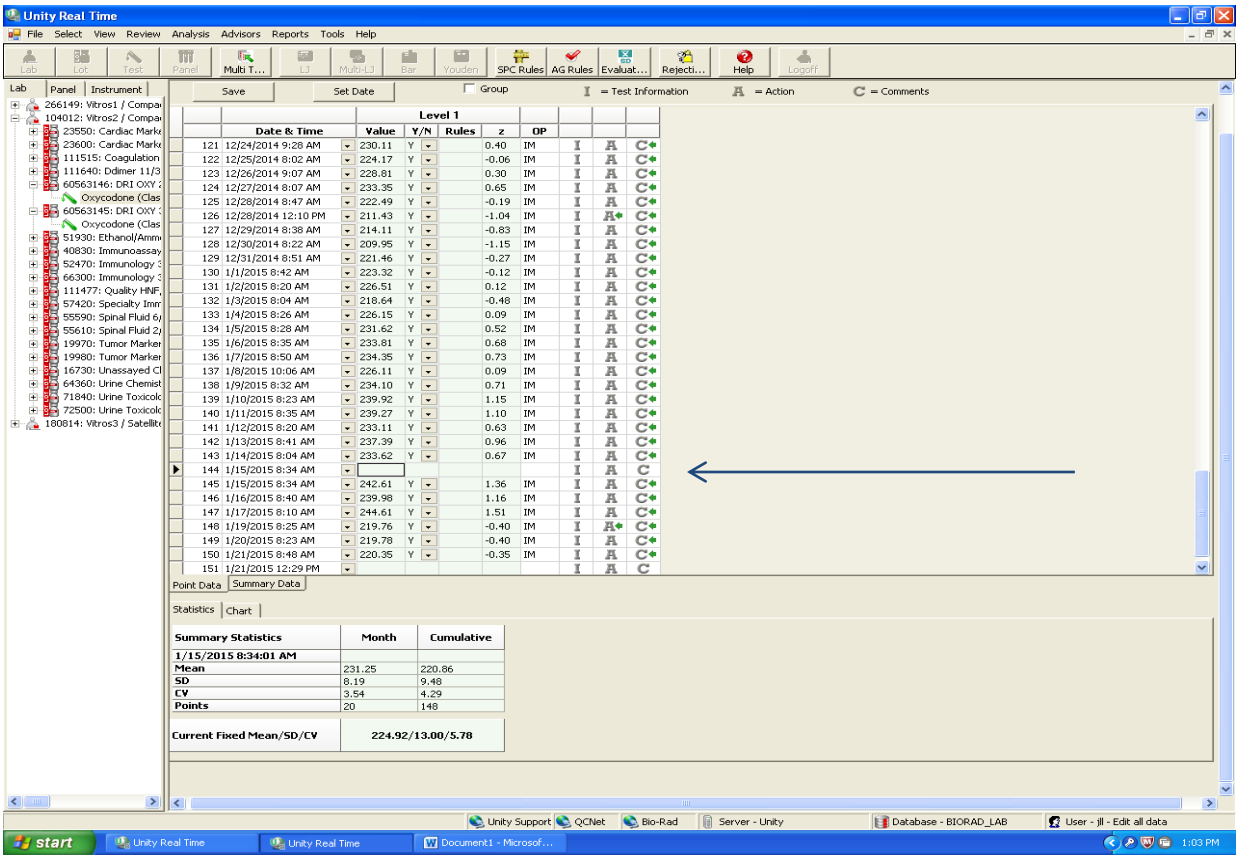


4. Select Yes

5. Now you have a line to add your data. Change date/time to accurately reflect QC run time.
   Note: Date and time, including AM or PM must be in the exact formatting as automatically posted results.

6. Enter data in the Value column(s). The Y/N Column is the Accept/Reject status (Y=Accept, N=Reject). Add an Action and/or Comment as appropriate and Click Save.

Line added for data



Note: For point data only, Unity Real Time 2.0 automatically adds a comment to the row stating the inserted data is not evaluated against SPC rules. A green arrow, **C** ⇐ appears for the row indicating the comment has been added. The operator's initials will be added in the OP column.
Note: Data points entered by manually inserting a data row will fall to the Bench Review screen after clicking Save. Users should complete the Bench Review task after entering data.

Single Test Point Data Entry

1. To manually enter data for a single test on a specific lot of QC, double-click a test in the Lab, Panel, or Instrument navigation tree. The Data Entry dialog box appears.

2. Select the last row and change date/time to accurately reflect QC run time.
   Note: To enter data for a previous date/time, see section Manually Insert a Data Row.

3. Enter data for all levels necessary and click Save.

Multi Test Point Data Entry

1. To manually enter data for multiple tests on a specific lot of QC, click the **Multi Test Data Entry** button in the toolbar.

2. Select the Lab, Instrument, Lot and Date/Time you want to enter data for using the dropdown boxes. Change date/time to accurately reflect QC run time.

3. Enter data for all tests/levels necessary and click Save.

SUPERVISOR REVIEW

Supervisor Review function allows supervisory personnel to retrospectively evaluate data.

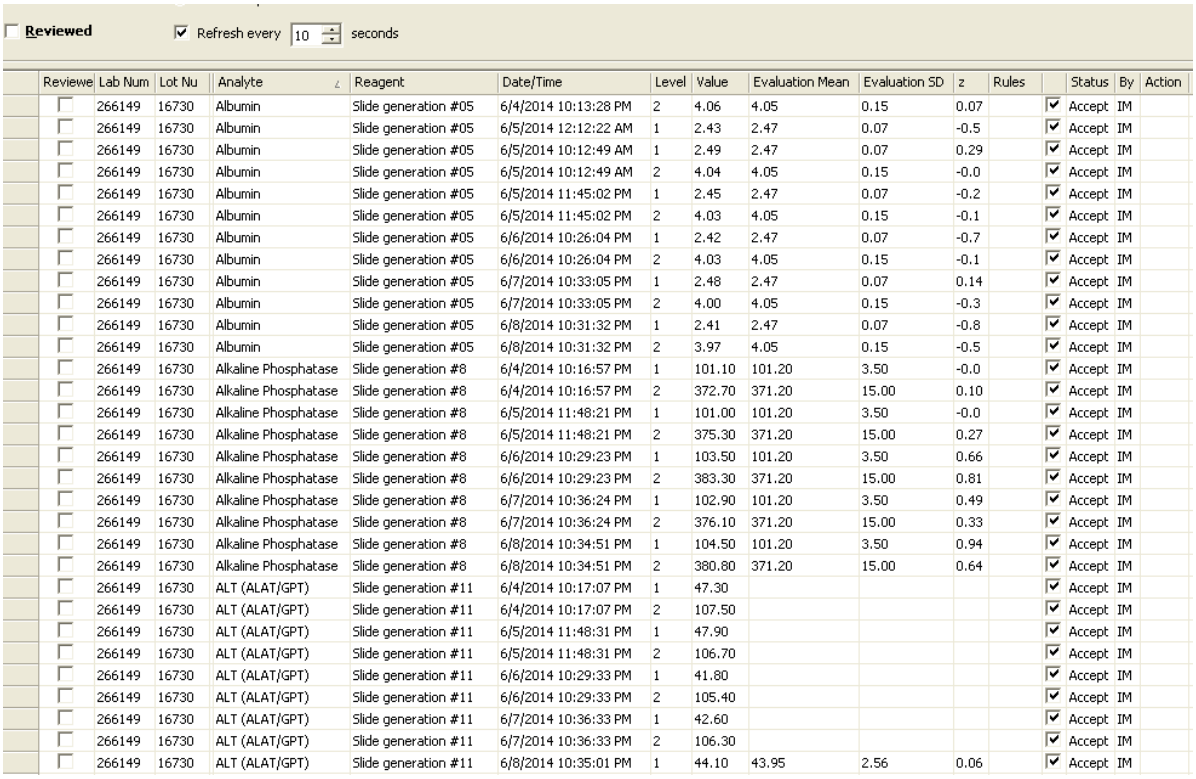
Supervisor Review supersedes Bench Review, this means that:

- Supervisor review will contain all un-reviewed data for a selected data set. This includes data that has not yet been reviewed in Bench review.
- Data reviewed from Supervisor Review is removed from Bench Review, even if it has not been reviewed from Bench Review

Procedure Notes

- During Bench Review ensure that an evaluation mean and SD is available for each test being reviewed. If the mean and SD field are blank, the Unity Software is NOT evaluating this QC against a fixed mean and SD, it is instead using a floating mean and SD to evaluate QC data.

1. To evaluate QC correctly, review the instrument QC data file for the analyte to determine the correct fixed mean (baseline mean) and SD. Ensure that current QC data is within 2 SD of the baseline mean from the instrument.
   2. Notify the Supervisor or Lead Tech to enter the fixed mean in the Unity system.



Reviewed Refresh every 10 seconds

Reviewe	Lab Num	Lot Nu	Analyte	Reagent	Date/Time	Level	Value	Evaluation Mean	Evaluation SD	z	Rules		Status	By	Action
☐	266149	16730	Albumin	Slide generation #05	6/4/2014 10:13:28 PM	2	4.06	4.05	0.15	0.07		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/5/2014 12:12:22 AM	1	2.43	2.47	0.07	-0.5		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/5/2014 10:12:49 AM	1	2.49	2.47	0.07	0.29		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/5/2014 10:12:49 AM	2	4.04	4.05	0.15	-0.0		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/5/2014 11:45:02 PM	1	2.45	2.47	0.07	-0.2		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/5/2014 11:45:02 PM	2	4.03	4.05	0.15	-0.1		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/6/2014 10:26:04 PM	1	2.42	2.47	0.07	-0.7		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/6/2014 10:26:04 PM	2	4.03	4.05	0.15	-0.1		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/7/2014 10:33:05 PM	1	2.48	2.47	0.07	0.14		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/7/2014 10:33:05 PM	2	4.00	4.05	0.15	-0.3		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/8/2014 10:31:32 PM	1	2.41	2.47	0.07	-0.8		☑	Accept	IM	
☐	266149	16730	Albumin	Slide generation #05	6/8/2014 10:31:32 PM	2	3.97	4.05	0.15	-0.5		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/4/2014 10:16:57 PM	1	101.10	101.20	3.50	-0.0		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/4/2014 10:16:57 PM	2	372.70	371.20	15.00	0.10		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/5/2014 11:48:21 PM	1	101.00	101.20	3.50	-0.0		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/5/2014 11:48:21 PM	2	375.30	371.20	15.00	0.27		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/6/2014 10:29:23 PM	1	103.50	101.20	3.50	0.66		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/6/2014 10:29:23 PM	2	383.30	371.20	15.00	0.81		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/7/2014 10:36:24 PM	1	102.90	101.20	3.50	0.49		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/7/2014 10:36:24 PM	2	376.10	371.20	15.00	0.33		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/8/2014 10:34:51 PM	1	104.50	101.20	3.50	0.94		☑	Accept	IM	
☐	266149	16730	Alkaline Phosphatase	Slide generation #8	6/8/2014 10:34:51 PM	2	380.80	371.20	15.00	0.64		☑	Accept	IM	
☐	266149	16730	ALT (ALAT/GPT)	Slide generation #11	6/4/2014 10:17:07 PM	1	47.30					☑	Accept	IM	
☐	266149	16730	ALT (ALAT/GPT)	Slide generation #11	6/4/2014 10:17:07 PM	2	107.50					☑	Accept	IM	
☐	266149	16730	ALT (ALAT/GPT)	Slide generation #11	6/5/2014 11:48:31 PM	1	47.90					☑	Accept	IM	
☐	266149	16730	ALT (ALAT/GPT)	Slide generation #11	6/5/2014 11:48:31 PM	2	106.70					☑	Accept	IM	
☐	266149	16730	ALT (ALAT/GPT)	Slide generation #11	6/6/2014 10:29:33 PM	1	41.80					☑	Accept	IM	
☐	266149	16730	ALT (ALAT/GPT)	Slide generation #11	6/6/2014 10:29:33 PM	2	105.40					☑	Accept	IM	
☐	266149	16730	ALT (ALAT/GPT)	Slide generation #11	6/7/2014 10:36:33 PM	1	42.60					☑	Accept	IM	
☐	266149	16730	ALT (ALAT/GPT)	Slide generation #11	6/7/2014 10:36:33 PM	2	106.30					☑	Accept	IM	
☐	266149	16730	ALT (ALAT/GPT)	Slide generation #11	6/8/2014 10:35:01 PM	1	44.10	43.95	2.56	0.06		☑	Accept	IM	

- All QC data must be programmed using the established naming conventions. If QC is not programmed correctly it will not appear in the Unity system. It is unacceptable to have valid QC that is not available for review in the system. If QC does not appear in Unity, it must be re-run with the correct naming conventions. It is not adequate to have merely an instrument printout in the QC file to document QC review.
- If the Accept/Reject status of a QC point is changed after Bench Review has been completed (such as during Supervisor Review), the data point will re-appear in the Bench Review screen.

REFERENCES

Unity Real Time Reference Guide for Expert QC Data Management, BioRad Laboratories. June 2006.
Unity Real Time 2, The Expert QC Data Management Solution, BioRad Laboratories August 2009.