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| Unity Real Time QC Review, General User |
| **Purpose** | The purpose of this procedure is to provide instruction on quality control review and troubleshooting in the Bio-Rad Unity Real Time (URT) 2.0 software. |
| **Policy Statements** | This procedure is intended for use by all personnel responsible for reviewing quality control on the chemistry instruments in the Auto Cell and Chemistry areas of the St. Paul and Minneapolis Laboratories. Quality controls are intended to detect errors in analytical test systems.**Do not load or run patients until QC has been entered into URT and reviewed, and all rule failures have been resolved, per CAP Regulations.**CAP requirements: * Controls are run at least daily, or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, for quantitative and qualitative tests, and when changes occur that may impact patient results.
* For quantitative tests, a valid acceptable range has been established or verified for each lot of control material.
* Quality control data are organized and presented so they can be evaluated daily by the technical staff to detect problems, trends, etc.
* There are records of corrective action when control results exceed defined acceptability Limits.
* Control specimens are tested in the same manner and by the same personnel as patient/ client samples.
* The results of controls are reviewed for acceptability before reporting results.
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| **Manual Data Entry, Single Test** | **Step** | **Action** |
|  | 1. 2
 | Under the Lab tab, click the + sign in the navigation tree to open the correct campus, then open the desired control by clicking the + or double-clicking the name of the control. Double-click on the test name to open the single-test data entry screen. |
|  |  | Ensure the **Point Data** tab is selected (at the bottom of the data entry screen)  |
|  | 1. 3
 | If needed, click the Set Date button to select the correct date and time. Note: data cannot be entered for a date and time prior to the last line of QC data. |
|  | 1. 4
 | In the new row, type the value for each level in the **Value** column under the correct control level, using the Tab or Enter key on the keyboard to move the cursor to the next level of control.  |
|  | 1. 5
 | If needed, press the Enter key on your keyboard to create a new row after you have completed the current row. |
|  | 1. 6
 | Click on the **Save** button when complete. (Top left) |
|  | 1. 7
 | Follow instructions for Bench Review, below. Note: once data is entered manually, it must also be reviewed under Bench Review.  |
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| **Manual Data Entry, Multi Test** | **Step** | **Action** |
| 1 | Under the Labs tab click the navigation tree to open the correct campus. Single click to highlight the desired control. |
| 2 | Click the  Multi-T… (Multi Test Data Entry) button on the top toolbar.  |
|  | 3 | Ensure the **Point Data** tab is selected (at the top of the data entry screen)  |
|  | 4 | If needed, make appropriate selections at the top of the screen for Date, Lab, and Lot. |
|  | 5 | Under the **Entered by:** select **Row or Level**. (Row allows entry of all levels for one test. Level allows entry of all tests, same level.) |
|  | 6 | Enter the values for the first test, using the Enter or Tab key to move to the next field or row. |
|  | 7 | Click the **Save** button when done. Top of data entry screen  |
|  | 8 | Follow instructions for Bench Review. Note: once data is entered manually, it must also be reviewed under bench review. |

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|  |  | **Note: Regardless of whether data is entered manually or is imported directly from the analyzers through the interface, all data must be reviewed for acceptability using the Bench Review function as described below prior to releasing patient results, per CAP Regulations**.  |
| Bench Review | **Step** | **Action** |
| 1 | Click **Review** on the menu bar, and from the drop down, select **Bench Review**. |
| 2 | Ensure the **Lab** “button” is selected.* With the All Data radio button selected, you will be reviewing all data for the selected quality control.

NOTE: The Refresh Every \_\_\_ Seconds box may be unchecked or the seconds increased to several minutes to provide time for reviewing the data. If the box is unchecked, no new data will appear until the box is re-checked. |
| 3 | From the drop down menus, select the appropriate campus, lot number, and instrument. Green text indicates there is data to review for the selection. |
| 4 | When reviewing data, the data is highlighted in one of four colors:* White: The data does not violate an SPC (Statistical Process Control) rule. Note: When running multiple levels of QC for a given test, if any of the levels fail, all levels will be rejected.
* Yellow: The data violates an SPC rule with a status of “Warn”. The data is automatically accepted, but can be unchecked to reject the data if warranted by troubleshooting.
* Red: The data violates an SPC rule with a status of “Reject.” The data is rejected. If multiple levels of control are run and only one level fails, both will be set to “reject.”
* Orange: The data violates an expected response setting for a qualitative test response. The data is rejected.

**Note: Warn and Reject failures** **must be investigated for cause and must have, at minimum, an action added. See the Add an Action or Comment and QC Troubleshooting sections, below.**Note: The z-score indicates how many standard deviations away from the expected mean the observed result falls. |
| 5 | To make the controls easier to view and review, right-click in the Analyte section of the header to “sort ascending”. |
| 6 | When all results have been reviewed and troubleshooting completed, check the box(es) under the Reviewed column.**Note: Use the laminated list of controls to make sure ALL levels of EVERY analyte have crossed into URT by marking each with a dry erase marker. When all controls are complete for your shift, wipe the check-off marks away using a tissue.** |
| 7 | Click Save, (bottom right corner)  |
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| Unity Real Time Downtime What to do if your QC does not cross into URT | If data is not crossing the interface to Unity Real Time bench review, notify the Technical Specialist of the downtime and receive further direction on how to proceed. If the problem can be resolved, data will automatically cross the interface from the instruments. If you cannot reach the Technical Specialist or if the problem cannot be resolved, enter the QC manually from all applicable test systems. Print the results from the automated analyzers and follow the **Manual Data Entry, Multi Test** or **Manual Data Entry, Single Test** data entry.**Do not load or run patients until QC has been entered into URT and reviewed, and all rule failures have been resolved, per CAP Regulations.** |
| Add an Action  | A documented Action is required in the case of any failed SPC/Westgard rules. |
| **Step** | **Action** |
| 1 | Click on the box in the Action Column for the specific analyte that is red/orange. |
|  | 2 | Pick an action from the menu  |
|  | 3 | Click apply |
|  | 4 | Click close  |
|  | 5 | The action will then be appended to all levels of that analyte Note: ADD A COMMENT with more details using free-text whenever possible.  |
| **Add a Comment** | The Comment field is for free-text comments. Add a Comment with as much detailed information as possible for rule failures, maintenance items, and any other necessary information pertaining to quality control. |
|  | **Step** | **Action** |
|  | 1 | Double-click on the box in the comment (or C) column for the specific analyte  |
|  | 2 | Type the comment you want to append in the white free text field |
|  | 3 | Click Apply  |
|  | 4 | Click Close  |
|  | 5 | The comment will then be appended to both levels of the analyte. |
| **Add an Action and/or Comment to All Results**  | Occasionally, a comment or action should be added to all tests or all lot numbers. For example, if the analyzer has preventative maintenance, or if the wrong level of QC is run. |
|  | **Step** | **Action** |
|  | 1 | From the tool bar, Click on Tools |
|  | 2 | Select Actions and Comments from the drop down menu |
|  | 3 | Select Action/Comment by Instrument from the drop down menu. The Actions and Comments by Instrument box appears |
|  | 4 | Click the box be either the action and or comment  |
|  | 5 | For actions click Add button, then find the appropriate action. Then click Apply and Close  |
|  | 6 | For comments, free-text your comment in the box provided |
|  | 7 | Choose the starting and ending date for the comment to be applied. |
|  | 8 | Under Scope: open the navigation tree to open the correct instrument |
|  | 9 | IMPORTANT: DO NOT SKIP THIS STEPClick the navigation tree to open to correct Lab location  |
|  | 10 | Single click the correct QC material and lot |
|  | 11 | Click OK |
| **QC Troubleshooting** | In the event a QC rule is triggered, INVESTIGATE by first making sure patient samples have not been loaded and will not be run during troubleshooting activities. Then, view the Levy-Jennings (LJ) chart (instructions given below) and consider the following factors:* Is the reagent volume low?
* Is the QC material volume low?
* Could there have been a bubble in the QC material or reagent?
* Is there a possible instrument pipetting error?
* Was a new lot of reagent loaded and/or is a new QC mean/SD/range needed?
* Is the system water functioning as expected or was there recent maintenance on the water?

If no reason for QC failure has been pinpointed, consider the following:* If QC material is low and the reagent volume is sufficient, open a new vial of QC.
* If QC material is sufficient and the reagent volume is low, replace the reagent on the instrument. Take off the old reagent.
* If QC materials AND reagent are insufficient or low, open a new vial of control for the repeat. If QC fails again, then replace the reagent and rerun QC.
* If QC materials and reagent are sufficient and all other possible causes have been eliminated, contact the Technical Specialist or the instrumentation technical support line.

Access the Levy-Jennings Chart 1. On the left panel, click on the Lab tab
2. Open the desired laboratory location
3. Open the current lot of QC
4. Double-click the desired test
5. Click on the LJ button

Access Peer Data1. Click Advisors on the top tool bar
2. Click Westgard… from the drop down menu. The Westgard Advisor box opens.
3. On the left, open the correct laboratory and lot number of control
4. Find the current lot of the analyte in question
5. In the top pane, make sure the correct analyte is highlighted find the analyte
6. Click the Group Statistics tab
7. Find the row for the Peer Monthly data for the desired level

**NOTE: Peer data is only available for controls manufactured Bio-Rad** |
| **Reset Passwords for Locked Accounts** | Several staff on each shift have access to unlocking accounts that have been locked due to repeated password entry failures. Please ask the Operations Supervisor, Technical Specialist or a coworker if a password needs to be reset. |
|  | 1. Select Tools from the upper menu bar
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|  | 1. Select Security from the drop down menu
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|  | 1. Select Administrator from the drop down menu
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|  | 1. Find the CE number in the drop down for the locked account tech number
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|  | 1. Click Unlock
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|  | 1. Enter new password: biorad1
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|  | 1. Click OK
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|  | 1. Tech can then log in with the temporary password to create a personal password.
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| **SPC Rules**  | Statistical Process Control (SPC) Rules are used to monitor test performance. For information on each QC rule, utilize the Unity Real Time software program for more details using the following steps:1. Click on the analyte in the Lab/Lot tree from the main screen of URT.
2. Click on the SPC Rules button  in the tool bar. The SPC Rules box will open.
3. Click on the Rule on the left side and a description of the rule will be visible on the right side of the pane.

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| Rule  | Error type  | When violated  | Notes  |
| 1-2s  | Random or systematic  | A single control observation is outside the ±2SD limit.  | When used as a rejection rule, 1-2s yields a high proportion of false rejections.  |
| 1-2.5s  | Random or systematic  | A single control observation is outside the ±2.5SD limit.  | This rule is applied within the run only.  |
| 1-3s  | Random or the beginning of large systematic  | A single control observation is outside the ±3SD limit.  | This rule is applied within the run only.  |
| 1-3.5s  | Random and may also indicate systematic  | One control value exceeds the mean ±3.5SD.  | This rule is applied within the run only.  |
| 1-4s  | Random and may also indicate systematic  | One control value exceeds the mean ±4SD.  | This rule is applied within the run only.  |
| 1-5s  | Random and may also indicate systematic  | One control value exceeds the mean ±5SD.  | This rule is applied within the run only.  |
| 2-2s  | Systematic  | Two consecutive QC results are outside the ±2SD limit on the same side of the mean.  | This rule is applied within and across runs.  |
| 2 of 3-2s  | Systematic  | Two of three levels of control within the same run exceed ±2SD on the same side of the mean.  | This rule is a variation of the 2-2s rule and is applicable when testing three or more levels of control material.  |
| R-4s  | Random  | There is at least a ±4SD difference between control values within a single run.  | Bio-Rad software uses the exact within-run difference between control values to determine if R4s is violated.  |
| 7-T  | Systematic  | Seven consecutive data points for a single level of control show either a “strict” increasing or decreasing pattern.  | A “strict” increasing pattern is defined as a series of points that increase incrementally from the previous point (each point greater than the last) without a break in the pattern. A “strict” decreasing pattern is the same pattern in the opposite direction.  |

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| **References** | 1. College of American Pathologists Chemistry and Toxicology Checklist, Northfield IL 60093-2750. 8/22/2018
2. Unity Real Time 2.0 User Guide, Bio-Rad Laboratories, Version 2.0 September 2017.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Stephen Gripentrog/ Erin Bartos | April 16, 2019 | New Procedure |
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