## TITLE: Manual Chemistry Quality Control in TQC

**PRINCIPLE**

Quality control material must be tested, reviewed, and reported correctly and in a timely manner to ensure the quality of the Chemistry Department patient results prior to verifying those results.

### REAGENTS AND SUPPLY REQUIREMENTS

Refer to the analyte’s individual Standard Operating Procedure and the Chemistry Quality Control Procedure #4840-CH-310.

**QUALITY CONTROL PRODUCTS AND INSTRUCTIONS FOR USE**

Refer to the Chemistry Quality Control Procedure #4840-CH-310

1. Manual chemistry testing (ROM Plus, Ketones and Body Fluid pH) QC is entered and reviewed in the Soft TQC program.

2. Body fluid pH and Ketone QC is run once every 24 hours when patient testing is performed.

3. Additionally, controls are run each time a new reagent is opened for patient testing.

4. ROM Plus external controls are run with each new lot number and once every 30 days for a current lot number.

5. Quality control is to be tested in the same manner as patient samples.

6. All control material should be treated as bio-hazardous material and discarded properly.

**MANAGING INVENTORY IN TQC**

1. When starting a new lot of quality control, receive the new lot of QC material into the

Soft TQC program. Refer to “Inventory Tasks-TQC” procedure (LIS #243) for details.

2. Test the new lot of control in the same manner as testing patient samples. Ensure the

new lot falls withn the acceptable QC ranges.

3. When the new lot of control is ready to be put in use, close the current lot of QC and

open the new lot of QC, Refer to “Inventory Tasks-TQC” procedure for details.

**PROCEDURE FOR MANUAL ENTRY OF ROM PLUS, KETONES AND pH**

1. For manual testing, there are Worklists in TQC that correspond to our Lab worklists.

2. From the Results dropdown or the Icon on the desktop chose Resulting Worklist.

3. Open the Template drop down (worklist) and choose the worklist you want,

click OK. If QC needs to be entered, the system will let you know that the current QC has expired or is unacceptable. There will be pending QC orders if this is the first patient order for pH or Ketone that was collected and received into the lab after midnight.

**NOTE: The specimen for any manual entry test MUST be collected and received before a QC ordered is generated in the Soft Lab worklist.**

4.If QC is required for a manual entry test, Soft will bridge you to the TQC Module.

5. The first screen indicates the Current QC results has Expired or is Pending.

A message appears in a small pop-up box. Click on the RedX in the small box.

Soft will then bridge to another screen which has the TQC resulting worklist.

6. Select the QC you will need to run and then click on Open.

7. Go to the resulting screen for the control. If the test you are resulting has a keypad

in Soft lab, it also has one in TQC. Enter the control result, if the QC is numeric type

in that result

8. Select” Verify” and” Save”.

9. You will be bridged from TQC back to SoftLab to enter your patient result.

**Entering QC results directly in to the TQC Module.**

1. In TQC, choose Result Entry in Results on the launch Bar.

2. When the screen opens, open the drop down for “From” date.

3. Change the date on the calendar to today’s date. You can select specific search criteria in the options listed below the dates to narrow the control list field. Click “Search” at the bottom of the panel.

4. The Results screen will open up with the list of orders that were created by the Scheduler.

5. To enter results into one of these orders, highlight the order and click on Open

6. The Order Entry Screen will open.

7. After entering the result, Click Verify (One or All) and then “Save”.

. 8. ” X” out of the Order –Result entry Screen in TQC.

**NOTE:**

1. All control results are to be reviewed immediately by the operator for acceptable

limits.

2. Patient testing results are not to be reported if control values are unacceptable.

3. Notify Lead Tech or designee of any problems.

4. Always indicate corrective action taken for any unacceptable QC value.

5. Accepted, rejected, and discarded results will be reviewed by the Senior Tech or designee at least weekly and all QC will be reviewed by the supervisor or designee at least once a month.

**STEPWISE PROCEDURE FOR REVIEWING RESULTS IN TQC:**

1. Open TQC module
2. Choose “**Review**” then “**Review Worklist**”. Review worklists have been set up by our TQC build team for each department to utilize an easier means of searching data and to keep track of the data in a uniform manner.
3. Choose the worklist “**CHEMQCREV-MANQC”:** Chemistry Daily QC Review-Manual QC.



1. Click on “**Search Criteria for Selected Worklist**”
2. Put in the date range you want to look at and click on **Search**, the system default only goes back three days.
3. All results in that date range come up. If there are any outliers, these results will be highlighted in yellow or red. For unacceptable results perform corrective action and repeat QC.
4. Click on “Select All” at the bottom of the page.
5. Click on the “**Review Orders**” tab at the right side, Click on the **Level 1** reviewed by button.
6. Choose your “**Action**” of **Reviewed** and say **Ok**.
7. The worklist will have green check marks by all the QC result lines that have been reviewed.
8. In the “**Status**” column, you will see there is a “**RV1**” by each line along with other letters. This indicates that they have been reviewed.
9. Close out that worklist and choose the next worklist: **CHEMQCRE-NV**, “**Chemistry Daily** **QC Review-Not Verified”**.
10. Click on “**Search Criteria**” at the bottom of the screen
11. Change your dates as desired, and click on “**Search**”
12. Any “**Pending and Overdue**” orders for QC will be on this list. If there are open QC orders, investigate why they are on the list and cancel if they are duplicates etc. Document with an action for any that are going to be cancelled.

16. The action of “**Reviewing Orders**” electronically puts the person logged into the system as the one who has reviewed the QC results from that worklist for those dates.

17. Daily QC review is not printed out; it is all electronically reviewed and documented by the system. Monthly QC is printed and reviewed by the Lead Tech or Designee.

18.To print a Monthly QC Data Report Retrieval for Review

A. In the Reports tab, select “**Results Report”.**

B.Click the **“Advanced Search”** tab on the bottom.

C.On the top of the page, select the appropriate template from the drop down box **“Result Report Templates”**.

D.From the drop-down box, select “CHEM-QC: Chemistry QC”.

E.Edit any of the Search criteria and /or scheduled date range if needed.

F. Press the Run Report box and select a local printer from the drop down box.

19. An action can be added to a result after it has been verified if needed.

1. In TQC, use Result Entry (either in the **RESULT** tab or **LOT RECORDS** tab) to select the control.
2. Double click on the correct order to open.
3. Click the **“EDIT”** icon.
4. Select the test and click the **“Result Action”** box.
5. On the bottom row of the top **“Result Action History**” box, click the

**“+”** sign.

1. Double click the box with the red “X” in the ID column.
2. Select the appropriate actions from the drop down box.
3. If additional comments are needed, click the box in the **“Comments”** column and freetext any additional comments, then click OK.
4. Press the **“OK”** box and **“SAVE”.**

**REFERENCES:**

ClIA 88” Regulations

SCC Total QC Module and Soft Lab.