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Area	Laboratory-Point of Care
Applicability	All Beaumont Hospitals

Point of Care Adding Quality Control Lot Numbers to Databases

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. This document describes the steps for Ancillary Testing staff to add quality control (QC) lot numbers to point of care (POC) databases.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PROCEDURE:

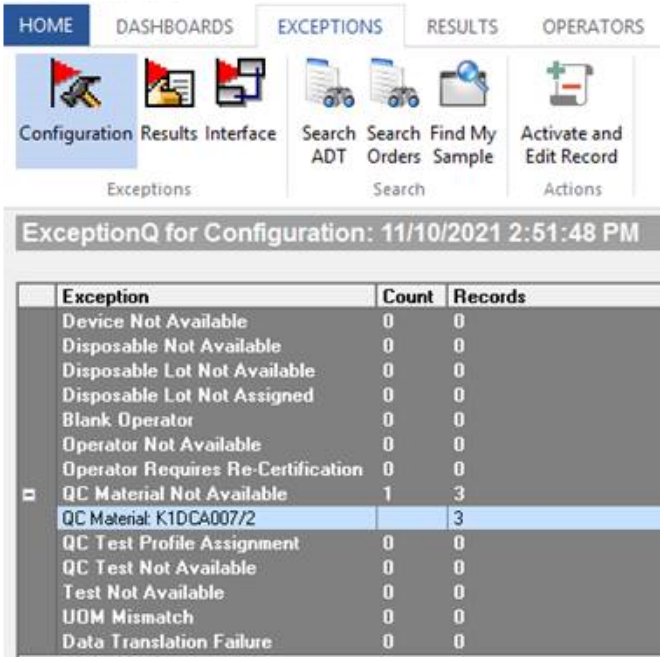
A. NovaNet (StatStrip Glucose)

1. Log in to NovaNet.
2. Select "Meter Setup" on the top to expand the menu options.
3. Click on "Reagents".
4. Press the "QC Lots" button to highlight the entire column.
5. Type in the lot number of the QC or calibration material on the "Lot Number" line and press the "Add Lot" button.
6. A message box will appear at the bottom of the page: "Set Lot Ranges for Facility". Verify the facility is set to "Royal Oak".
7. Enter the low and high values that are on the QC or calibration vial.
    a. Enter "X" for tests/ranges that are not used.
8. Press "Save".

9. Highlight the lot number that was just entered (under the "QC Lots" column) and select the appropriate Royal Oak testing locations on the left.
10. Press "Click Here to Save Reagent Assignments".

B. HemoCue DMS (HemoCue)
    1. Log in to the HemoCue software on the designated HemoCue computer.
    2. Navigate to "Hb Settings" > "Liquid Controls".
    3. Select either "Level 1 (Low)" or "Level 3 (High)".
    4. Press "Edit" > "New".
    5. Select the control name "RNA Medical".
    6. Enter the lot number and expiration date.
    7. Set the "Warning" to "Min and Max".
    8. Set the "Lockout" to "Min and Max".
    9. Press "Save".
    10. Navigate to "Analyzers" and highlight each analyzer group > "Analyzer" > "Send to Group" > "Liquid Controls".
    11. Lock the computer when done.

C. QML (GEM Hemochron 100, Hemochron Signature Elite, HemoCue, StatStrip, Piccolo)
    1. QC Results Downloaded to QML
        a. Run the new lot of QC.
        b. Log in to QML.
        c. Navigate to "Exceptions" > "Configuration". New lots of QC will fall into "QC Material Not Available".



d. Click the "+" next to "QC Material Not Available" and select the record (highlight the line) pertaining to the new lot of QC material.

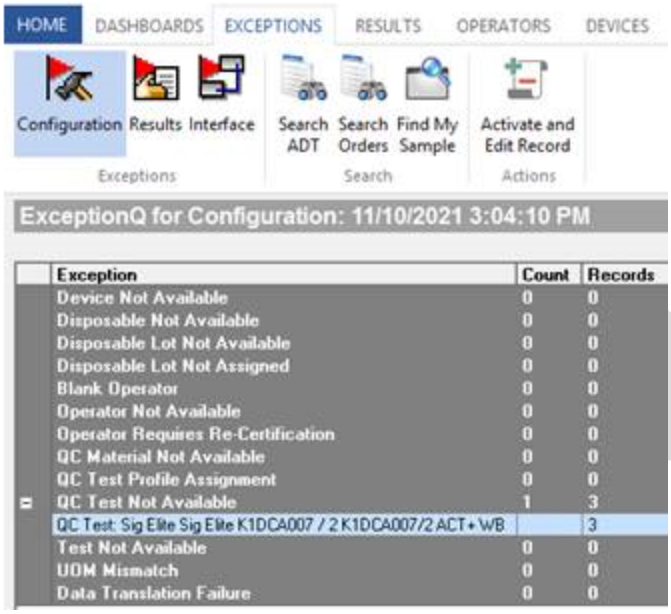
e. Press the "Activate and Edit" button on the top of the screen. This will open the "Configuration Summary-QC Material" screen.

f. Find the new lot of QC and fill out the applicable information related to the QC material (i.e. start date (date the QC was received), expiration date, end date (expiration date)).

    i. If the new lot of QC does not display in the "QC Material Configuration Detail" screen, select "New" and complete the QC profile information for the new QC lot.

g. Press "Save".

h. Navigate back to "Exceptions" > "Configuration" to confirm that the new lot of QC has moved to "QC Test Not Available".



i. Press the "+" next to the new lot of QC and select (highlight the line) the QC record then press "Activate and Edit Record". This action will open the "Configuration Summary-QC Test" page.

j. Find the new lot of QC and select the record by double-clicking on the corresponding line for the QC lot. This will open the "Configuration Detail-QC Test" page.

k. Change the Range Style to "Range with Mean and SD".

l. Click on the drop-down next to "QC Flag Profile" and select the device applicable to the QC.

m. Manually enter the QC ranges in the "Low" and "High" fields under Numeric Ranges. The mean and SD will automatically populate.

n. Press "Save".

    i. Note: The Piccolo does not send liquid QC values to QML. The 2

levels of QC should remain as level "0". Do not edit the "Level" field for the Piccolo QC.

o. Once the item is closed, verify that the values are corrected before leaving QML.

2. QC Not Appearing in the Configuration ExceptionQ (ABL80, ABL90)
    a. See instrument-specific procedures for instructions on scanning/entering new lots of QC and ranges into the instruments.
    b. Log in to QML.
    c. Select the "Test" tab.
    d. Select "QC Materials".
    e. If the desired lot is not listed on the "QC Materials" page, press "New".
        i. Device Type: Select "Radiometer" from the drop-down menu.
        ii. Lot: Manually enter the lot number.
        iii. Level: Choose the appropriate level of QC from the drop-down menu (1, 2, or 3).
        iv. Start Date: Enter the date that the QC was received or first assayed on an instrument.
        v. Expiration Date: Enter the manufacturer's expiration date.
        vi. End Date: Enter the manufacturer's expiration date.
        vii. Press "Save".
        viii. Under "QC Test Profiles", enter a "Profile Name" for each level in the following format: "Radiometer XXX (lot number of QC) / X (level of QC)".
        ix. Press "Save".
    f. Select "QC Tests".
    g. Find the lot number to be configured by using the "Find" feature or by sorting through the lot numbers in the list. Double-click on the lot to be configured.
        i. Change the "Range Style" from the drop-down menu to "Range with Mean and SD".
        ii. QC Flag Profile: Choose "Radiometer" from the drop-down menu.
        iii. Numeric Ranges: Add as many lines as needed to drop in the following "Test Codes" from the drop-down menu:
            a. pH(T)
            b. po2(T)
            c. pco2(T)
            d. R tHb

e. O2Hb
f. COHb
g. MetHb
h. K+
i. Na+
j. Ca++
k. Cl-
l. R Glu
m. Lac
n. tBil

i. Only select the analytes performed at the specific testing site.

iv. Type in the lower and upper limits of the QC level for each analyte as listed in the QC package insert into the "Low" and "High" fields in QML.

h. Press "Save".

i. The ABL80 and ABL90 uses the same test codes for R tHb and O2Hb. Configuring lots for the ABL90 will cover the ranges needed for the ABL80. Always pick the most conservative range listed on the package insert between the two instruments as the ranges may vary slightly between the two devices.

Attachments

b64_2ecec8af-1a0a-4735-ae06-52657bcaf4cf

b64_f00a9efa-d39a-4f76-817e-bf3d3504c821

b64_f5265ac6-81fa-4725-8329-3ad828b3d2cc

Approval Signatures

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CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	6/12/2023
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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne