

Beaumont

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Applicability All Beaumont Hospitals

Point of Care Adding Reagent Lot Numbers to Databases

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

- A. This document describes the steps for Point of Care Testing staff to add reagent 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 "Strip Lots" button to highlight the entire column.
 - 5. Type in the lot number of the reagent on the "Lot Number" line and press the "Add Lot" button.
 - 6. Highlight the lot number that was just entered (under the "Strip Lots" column) and select the appropriate campus testing locations on the left.
 - 7. Press "Click Here to Save Reagent Assignments".
- B. MTE (Urine Dipstick, Urine Pregnancy)
 - 1. NovaNet locations are set-up as follows; do not change these settings.
 - a. Select "Meter Setup" on the top to expand the menu options.

- b. Click on "Manual Test Setup".
- c. Highlight the meter's NovaNet location (OP SERVICES) and place a "\/" in the boxes next to the following items:
 - i. Require Validation: Card/Kit Lot
 - ii. Allow Not Validated: Card/Kit Lot
 - iii. Lot Lists: Card/Kit Lot
- d. Press "Click Here to Save Profile to Selected Locations".

2. Enter New Lot Number

- a. Select "Meter Setup" on the top to expand the menu options.
- b. Click on "Manual Test Lots".
- c. Under "Select Tests", use the drop-down menu to pick the correct test.
- d. Enter the correct data in the "Lot Number" and "Expiration Date" fields.
 - i. Note: The "Start Date" is the date the item was received. The "End Date" is the expiration date.
- e. Press the "Add Lot" button.

3. Assign New Lot Number

- a. Select "Meter Setup" on the top to expand the menu options.
- b. Click on "Reagents".
- c. Press the "Show Manual Test Lots" button.
- d. Click to highlight a location on the left and the new lot number should appear.
- e. Highlight the correct lot number.
- f. Press "Click Here to Save Reagent Assignments".
- g. Repeat steps d-f for each desired location, including "TRAINING".

C. QML for Liat

1. Run QC on the new lot of assay tube.
2. Log in to QML and click on the "Configuration Exceptions" tile on the QML Tile page.
3. Press the "+" next to "Disposable Lot Not Available" to display the records in this section. Select the line related to the new lot. Press the "Activate and Edit" button.
4. Fill in the information related to the new lot and press "Save".

Configuration Detail - Disposable Lot - 10809T	
Definition	Notes
Device Type	Liat
Disposable	SARSCV2
Disposable Lot	10809T
Start Date	10/1/2021
Expiration Date	7/31/2022
End Date	7/31/2022
Vendor Bar Code	Valued
Vendor Device Parameters	Valued
Vendor Minimum Version	1.0
Vendor Validation Date	2021-10-15T12:47:19-04:00
Vendor Digital Signature	Valued
Status	Active
Last Updated	10/19/2021 8:24:40 AM
Last Updated By	SUPPORT

5. Press the "+" next to "Disposable Lot Not Assigned", select the correct record, and press the "Activate and Edit" button.
6. QML will display the only active disposable profile. Double-click on the disposable profile.



Configuration Summary - Disposable Profile		
Status	Profile Name	Location Type
Active	Liat	Selected Locations

7. The "Configuration Detail - Disposable Profile - Liat" screen will open. Press the magnifying glass next to "Test Material" and fill in the assay reagent information.
 - a. Select "Add Line" and use the drop-down menus for the options below:
 - i. Device Type: "Liat"
 - ii. Disposable: "SARSFLU" or "SARS" (depending on current reagent use)
 - iii. Material Lot: Select the applicable assay lot. Enter the "Start Date", "Expiration Date", and "End Date".
 - a. Note: The "Start Date" is the date the assay tube was received. The "End Date" is the expiration date.
8. Press "Save".

D. QML for WebMRE (CoaguChek, Urine Dipstick, Urine Pregnancy, Nova Xpress)

1. Navigate to "Device Type".
2. Press "Disposable Lot".
3. Press "New".
4. Use the "Device Type" drop-down menu to select the manual test/kit.
5. Enter the "Disposable Lot" and "Expiration Date".
6. Press "Save".
7. Log out of QML. Log back in to QML with the ID "12345" and password "poc".
8. Navigate to the "Home" tab. Press "Sync WebMRE".

9. Wait for the "Sync Completed" pop-up to appear and select "OK".

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	6/14/2023
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	5/31/2023
CLIA Medical Directors	Muhammad Arshad: Physician	5/25/2023
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	5/25/2023
CLIA Medical Directors	John Pui: Chief, Pathology	5/24/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	5/24/2023
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	5/24/2023
	Caitlin Schein: Staff Physician	5/24/2023
Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	5/19/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	5/19/2023
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Applicability

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