PROCEDURE
Corewell Health East - Loading Oxycodone c4000 - Taylor, Trenton, Wayne

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Chemistry

1. Principle
The following procedure describes the process used to load Oxycodone (OxyQ) reagent on the Abbott Architect c4000 analyzers. The Oxycodone reagent is a user defined reagent that is manufactured by Immunalysis Corporation orderable through Abbott Diagnostics. This assay is intended for use in laboratories for the qualitative analysis of Oxycodone in human urine with automated clinical chemistry analyzers.

2. Responsibility
Personnel who have completed the competency requirements will perform this testing.

3. Reagent/Equipment Needed
A. Oxycodone Reagent Pack: 25 mL Antibody/Substrate Reagent (A), 25 mL Enzyme Conjugate Reagent (E).
B. 55 mL Abbott Architect Cartridges (2)
C. Disposable Pipettes
D. This procedure document is only intended for the Abbott Architect c4000.

4. Procedure
A. Reagent Preparation
   1. Transfer 25 ml Antibody/Substrate Reagent (A) into a labeled 55 mL cartridge.
   2. Transfer 25 mL Enzyme Conjugate Reagent (E) into a labeled 55 mL cartridge.

B. Log in the Architect c4000 as the Administrator to configure the User Defined Reagent. Username:**ADMIN**, Password: **ADM.**

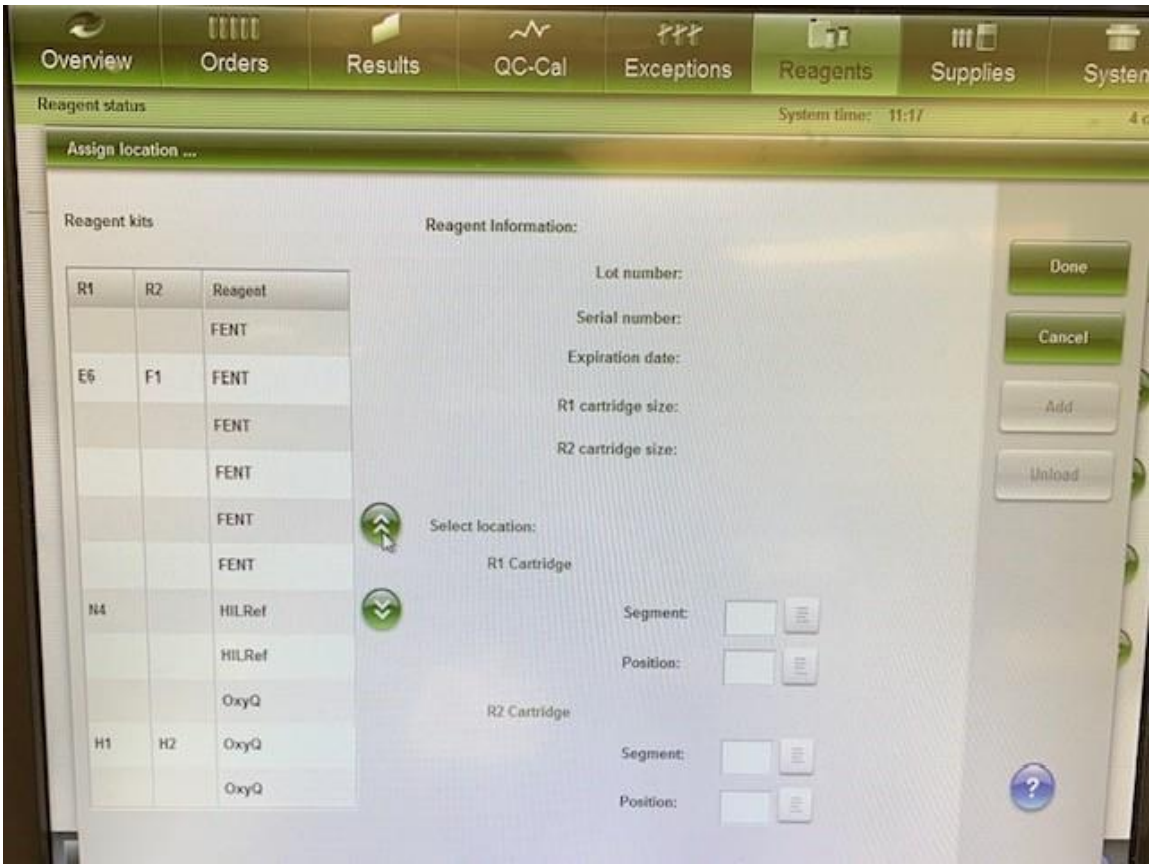
C. To Configure a User-Defined Reagent:
   1. Select "**System"** on the main screen then "**Configuration"**.
   2. Select assay "**Assay Settings"** at the top of the Configuration screen, then Select "**Reagent Settings"** on the left-hand side.
   3. Select assay "**OXYQ**" and then select "**F6 Configure".**
   4. On the configuration screen, either: Select **"New Lot"** and enter a new lot number in the Lot number data Entry box OR Select the desired lot from the list.
   5. Enter a unique number in the Serial number data entry box.

a. Note: Multiple serial numbers for each lot number can be entered to allow you to load multiple kits of the same reagent. Each kit defined for a single lot number must have a unique numeric identifier (serial number). One suggestion is using the month and day that the kit was loaded on the instrument.

6. Enter a date in the Expiration date data entry box.
7. Select the R1 cartridge size list button, and then select the cartridge size 55 mL.
8. Select the R2 cartridge size list button, and then select the cartridge size 55 mL.
9. Select "**Add kit"** to create the kit. The new kit is displayed in the Configured kits list.
10. Select **"Done"** to save changes.

D. To Load Reagent

1. The instrument must be in the '**Ready**' state.
2. On the Abbott Architect screen, select "**Reagents**" tab at the Top of the screen, then select "**Reagent Status**".
3. On the Reagent Status screen select "**Assign Location**" at the bottom of the screen.
4. Select "**OXYQ"** on the left-hand side of the screen, then select "**Unload**" to unload any empty reagent cartridge.
5. Place the new cartridges in any open slots on the reagent wheel.
6. Select reagent kit, verify current lot and serial number.
7. Select segment and position for R1 and R2 cartridges.
8. Select "**Add**" on the right-hand side of the screen, then select "**Done**".
9. Refer to screen shot below for visual.
10. If the reagent lot number is the same, **"Reset"** may be selected on the reagents screen to reset the volume and stability. If the kit on board has gone all the way to ZERO tests, "Reset" will not be available and a new reagent will need to be configured (See D above).



5. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

6. Procedure Development and Approval

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7. Keywords

Not Set