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Loading Fentanyl c4000

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The following procedure describes the process used to load Fentanyl (FENII) reagent on the Abbott Architect c4000 analyzers. The Fentanyl II reagent is a user defined reagent that is manufactured by Ark Diagnostics orderable through Sekisui. This assay provides a simple and rapid analytical screening procedure for detecting Fentanyl in urine.

II. REAGENTS:

- A. Fentanyl II Reagent Pack Contents: 28 mL Antibody/Substrate (R1) and 28 mL Enzyme Reagent (R2)

III. EQUIPMENT:

This procedure document is only intended for the Abbott Architect c4000

IV. SUPPLIES:

- A. 55 mL Abbott Architect Cartridges
- B. Disposable Pipettes

V. PROCEDURE:

- A. Reagent Preparation
 1. Transfer 28 mL Antibody/Substrate (R1) into a labeled 55 mL cartridge.
 2. Transfer 28 mL Enzyme (R2) into another labeled 55 mL cartridge.

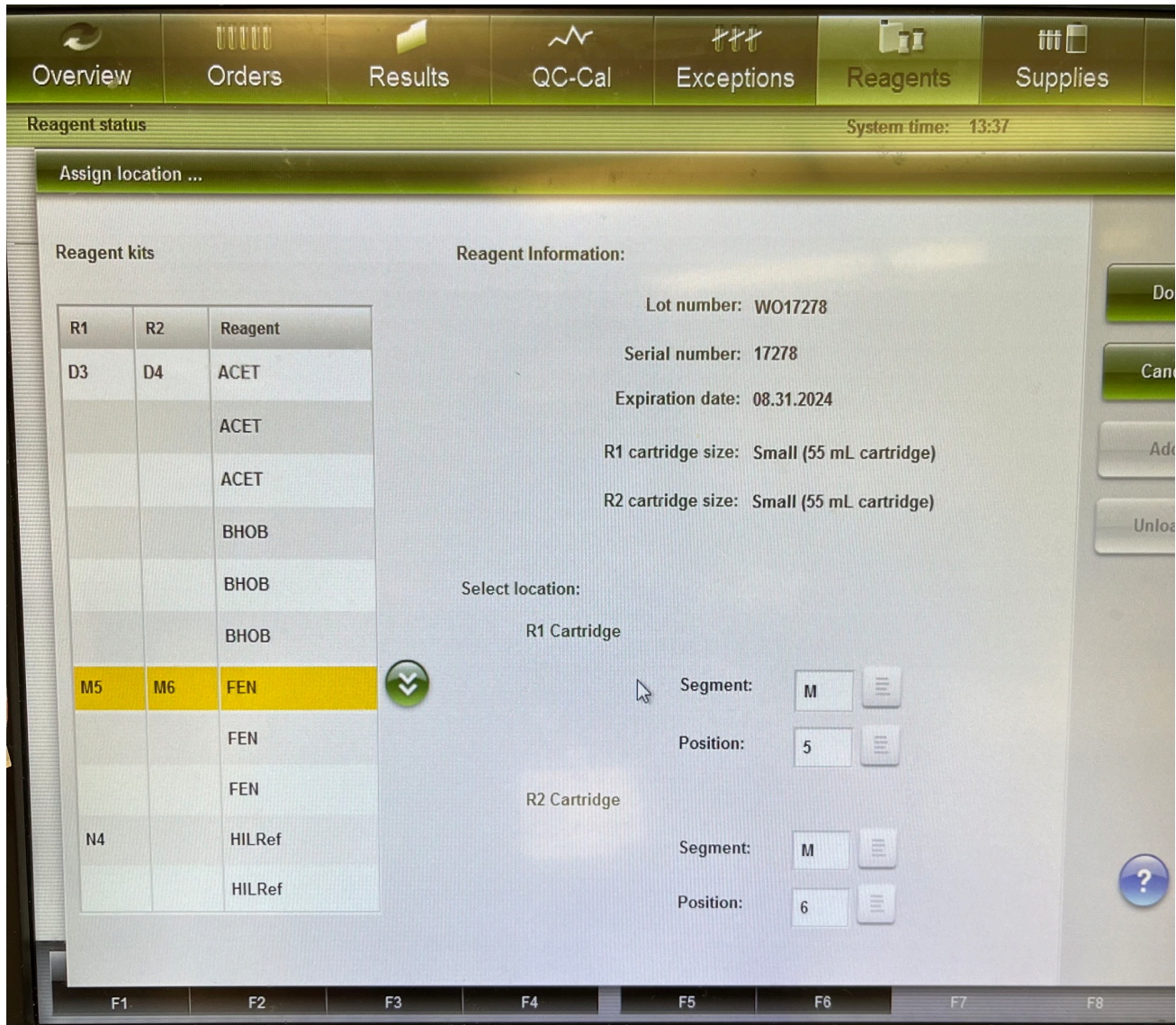
B. Log into the Architect c4000 as the Administrator to configure the User Defined Reagent-
Username: **ADMIN**, Password: **ADM**.

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 "**FENII**" 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.
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).
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 displays in the Configured kits list.
10. Select **Done** to save changes.

D. To Load Reagent

1. 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 "**FENII**" 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).



Approval Signatures

Step Description	Approver	Date
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Applicability

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