

PROCEDURE

Corewell Health East Loading User-Defined Reagent 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
Reference #:	34338
Version #:	2
Effective Date:	10/09/2025
Functional Area:	Clinical Operations, Laboratory
Lab Department Area:	Lab - Chemistry

1. Principle

The following procedure describes the process used to load User-defined reagents on the Abbott Architect c4000 analyzers.

- A. The Beta-hydroxybutyrate (BHOB) reagent is a user-defined reagent that is manufactured by Fisher Healthcare. BHOB reagent is used to detect ketones to identify patients suffering from diabetic ketoacidosis, amongst many other clinical applications.
- B. The Fentanyl II reagent is a user-defined reagent that is manufactured by Ark Diagnostics and is orderable through Sekisui. This assay provides a simple and rapid analytical screening procedure for detecting Fentanyl in urine.
- C. The Oxycodone reagent is a user-defined reagent that is manufactured by Immunalysis Corporation and is orderable through Abbott Diagnostics. This assay is intended for the qualitative analysis of Oxycodone in human urine with automated clinical chemistry analyzers.
- D. Saline is treated as a user-defined solution on the reagent wheel. One cartridge is built to be used for on-board dilutions (Saline) and one cartridge is built to be used as a blank for HIL (Hemolysis, Icterus, Lipemia) testing (HIL Ref).

2. Responsibility

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

3. Reagent/Equipment Needed

- A. BHOB Reagent Pack REF: 23001176 (Contents: 50 mL Enzyme Reagent (R1), 8.5 mL Catalyst Reagent (R2), and a 3 mL Standard).
 1. 55 mL Abbott Architect Cartridge.
 2. 20 mL Abbott Architect Cartridge.
- B. Fentanyl II Reagent Pack (Contents: 38 mL Antibody/Substrate Reagent (R1) and 28 mL Enzyme Reagent (R2)).
 1. 55 mL Abbott Architect Cartridge (2)
- C. Oxycodone Reagent Pack (Contents: 25 mL Antibody/Substrate Reagent (A) and 25 mL Enzyme Conjugate Reagent (E)).
 1. 55 mL Abbott Architect Cartridge (2)

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- D. Saline-Blood Bank Saline
 - 1. 90 mL Abbott Architect Cartridge (2)
- E. Disposable Pipettes
- F. This procedure document is only intended for the Abbott Architect c4000.

4. Procedure

- A. Reagent Preparation
 - 1. BHOB
 - a. Transfer BHOB Enzyme (R1) into a properly labeled 55 mL cartridge.
 - b. Transfer BHOB Catalyst (R2) into a properly labeled 20 mL cartridge.
 - 2. Fentanyl II and Oxycodone
 - a. Transfer each reagent into a properly labeled 55 mL cartridge.
 - 3. Saline / HIL Ref
 - a. Fill a properly labeled 90 mL cartridge with Blood Bank Saline for each solution. Fill to the line on the cartridge. Do not overfill.
- 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 you are configuring 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 drop-down list of previously configured lot numbers.
 - a. Note: Saline and HIL REF cartridges cannot be configured using the same lot number. You can add an "S" to the end of one of the lots.
 - 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 lot of reagent. Each kit defined for a single lot number must have a unique numeric identifier (serial number). A possible example could be the month and day the reagent was configured.
 - 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 (See Reagent Preparation section above).
 - 8. Select the R2 cartridge size list button, and then select the cartridge size (See Reagent Preparation section above).
 - 9. Select **"Add kit"** to create the kit. The new kit information will be displayed in the Configured kits list.
 - 10. Select **Done** to save changes.
 - 11. Once a reagent is no longer in use, the configured reagent can be deleted by highlighting the configured kit and selecting **"Delete kit"**. The instrument must be in the **"Ready"** state.
 - 12. Note: It is important that you configure the correct cartridge size (Steps 7 and 8) in order for the test counts to be accurate on the Reagent Status screen.
- D. To Load Reagent
 - 1. The instrument must 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 the reagent on the left-hand side of the screen that you want to load.
 - a. Verify that the lot number and serial number match what was just configured.
 - 5. Locate an open spot on the reagent wheel for each of the reagent cartridges.
 - 6. Select the open segment and position for R1 and R2 cartridges from the drop-down menus.
 - 7. Select **"Add"** on the right-hand side of the screen, then select **"Done"**.

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- a. Note: To remove a reagent from the reagent wheel:
 - 1) Locate the reagent on the left-hand side of the screen.
 - 2) Verify the lot number and serial number.
 - 3) Select “**Unload**” to unload any empty reagent cartridge.
 - 4) Alternatively, if you put a barcoded reagent cartridge in the same spot that a user-defined reagent was configured, the user-defined reagent will be overridden when the reagent wheel is scanned, and a pop-up message will appear letting you know the user-defined kit was removed.
8. Refer to screen shot below for visual.



E. Reset

1. If the reagent lot number is the same, “**Reset**” may be selected on the reagents screen to reset the volume and stability. This is especially useful for the Saline and HIL Ref cartridges when they are being refilled with the same lot of saline.
2. If the test count has reached zero tests, “**Reset**” will not be available and a new reagent cartridge will need to be configured. See above.

5. Revisions

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

6. Procedures Superseded and Replaced: This procedure supersedes and replaces the following procedures as of the effective date of this procedure: [34340 Corewell Health East – Loading

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Oxycodone c4000 – Taylor, Trenton, Wayne, 34339 Corewell Health East – Loading Fentanyl c4000 – Taylor, Trenton, Wayne]

7. Procedure Development and Approval

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8. Keywords

Not Set