TITLE: BECKMAN Coulter user defined reagent (udr) operating procedure

**PRINCIPLE / PURPOSE:** User defined reagents are non-Beckman Coulter branded reagents produced by 3rd party manufacturers that are approved for use on Beckman Coulter UniCel, DxC and Synchron analyzers.

**SCOPE:** This procedure is a basic operating guide for technologists/technicians performing testing on Beckman Unicel DxC analyzers that are testing patients with User Defined Reagents.

**COMPLEXITY LEVEL:** Moderate

**SAFETY:**

* The required personal protective equipment for this procedure
  + - Gloves
    - Impermeable lab coats, worn closed
    - Shield
    - Approved protective eyewear
* Gloves and lab coats should be worn at all times during analysis of the samples.
* Samples must be opened behind a safety shield.

**EQUIPMENT AND MATERIALS:** See applicable assay sheet

***Assay Methodology/Clinical Significance:*** See Cone Health “Clinical Chemistry Information Sheet” for a list of assays performed, sample size, linearity (AMR), manual dilution, unit of measure, reportable range (CRR), Reference Range, and Critical Value list.

See assay specific Beckman UniCel “DxC Systems Chemistry Information Sheets” or manufacturer’s package insert sheets for assay methodology and clinical significance.

**Microgenics DRI Tricyclics Serum Tox Assay**

The DRI Tricyclics serum Tox Assay kit contains enough reagent to prepare two cartridges of useable reagent.

* 25 mL of Antibody/Substrate reagent
* 8 mL of Enzyme Conjugate reagent

1. Label a new UDR cartridge with STCX, both of the reagent lot numbers and expiration date as well as preparation date and employee initials.
2. Pipette 12.5 mL of Antibody/Substrate reagent into compartment B of the UDR.
3. Pipette 4 mL of Enzyme Conjugate reagent into compartment C of the UDR.
4. Load the UDR into a CC position of the analyzer in a free position between 31-59 per Beckman Coulter recommendations and utilize load instructions listed in procedure CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600).
5. Since the UDR is not barcoded, when prompted by the analyzer type in “STCX” for the reagent name.
6. The analyzer will only accept six digits of the lot number information, type in the last six digits of the lot number into the provided space.
7. The reagent does not come from the manufacturer with a serial number, tech initials should be used.
8. Enter the two digit month and two digit expiration of the reagent and press tab.
9. Calibrate if prompted by the analyzer per calibration procedure listed in CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600).
10. Perform Quality Control of reagent per procedure listed in CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600).
11. Once onboard the instrument, the reagent will be stable for 60 days.
12. Record load date and expiration on UDR log. Original expiration date is on the kit box.

**Thermo Scientific Infinity Lithium Reagent**

The Infinity Lithium reagent kit contains enough reagent and pre-labeled UDR cartridges to prepare two cartridges of useable reagent.

* Two 18 mL bottles of Infinity Lithium reagent
* Two pre-labeled UDR cartridges

1. Label one of the Lithium UDR cartridges provided with the preparation date and employee initials.
2. Transfer the entire contents of the Lithium reagent into compartment B of the provided cartridge.
3. Load the UDR into the CC module of the analyzer using a free position between 31-59 per Beckman Coulter recommendations and utilize load instructions listed in procedure CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600).
4. Calibrate if prompted by the analyzer per calibration procedure listed in CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600). Refer to the Beckman Calibrator Chart for calibrators to use.
5. Perform Quality Control of reagent per procedure listed in CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600). Refer to the site specific QC frequency chart for QC material required.
6. Once onboard the instrument, the reagent will be stable for 14 days.

**Thermo Scientific DRI Ecstasy Assay Reagent**

The DRI Ecstasy (XTCX) reagent kit contains enough reagent to prepare two useable cartridges

* One 100 mL bottle of reagent (A) Antibody/Substrate Reagent
* One 100 mL bottle of reagent (E) Enzyme Conjugate Reagent

1. Pipette 48 mL of antibody/substrate reagent A into compartment A of the UDR cartridge.
2. Pipette 18 mL of enzyme conjugate reagent E into compartment B of the UDR cartridge.
3. Label the cartridge with date of preparation and employee initials, lot #, lot expiration date (located on box of the kit).
4. The remaining unused volume left in the two primary reagent bottles should be disposed of per proper waste handling instructions.
5. Load the UDR into a CC position of the analyzer in a free position between 31-59 per Beckman Coulter recommendations and utilize load instructions listed in procedure CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600).
6. Since the UDR is not barcoded, when prompted by the analyzer type in “XTXC” for the reagent name.
7. The analyzer will only accept six digits of the lot number information, type in the last six digits of the lot number into the provided space.
8. The reagent does not come from the manufacturer with a serial number, tech initials should be used.
9. Enter the two digit month and two digit expiration of the reagent and press tab.
10. Calibrate if prompted by the analyzer per calibration procedure listed in CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600). Refer to the Beckman Calibrator Chart for calibrators to use.
11. Perform Quality Control of reagent per procedure listed in CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600). Refer to the site specific QC frequency chart for QC material required.
12. Once onboard the instrument, the reagent will be stable for 60 days.
13. Record load date and expiration on UDR log.

**Stanbio Betahydroxybuteric Acid Reagent**

The Stanbio Betahydroxybuteric Acid (BHOB) kit contains enough reagent to prepare three useable cartridges.

* One 50 mL bottle of B-Hydroxybutyrate Enzme (R1)
* One 8.5 mL bottle of B-Hydroxybutyrate Catalyst (R2)

1. Pipette 16 mL of R1 reagent into position B of the UDR cartridge.
2. Use the appropriate pipettes to transfer 2.8 mL of R2 reagent into position C of the UDR cartridge.
3. Label the cartridge with date of preparation, employee initials and expiration date.
4. Reagent leftover in the primary bottles should be placed back into the refrigerator in the original box.
5. Load the UDR into a free CC position of the analyzer using load instructions listed in procedure CHEM-0366-CH (DxC 600) and CHEM-0365-MC (DxC 800).
6. Since the UDR is not barcoded, when prompted by the analyzer type in “BHOB” for the reagent name.
7. The analyzer will only accept six digits of the lot number information, type in the last six digits of the lot number into the provided space.
8. The reagent does not come from the manufacturer with a serial number, initial should be used.
9. Enter the two digit month and two digit expiration of the reagent and press tab.
10. Calibrate the analyzer per calibration procedure listed in CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600). Refer to the Beckman Calibrator Chart for calibrators to use.
11. Perform Quality Control of reagent per procedure listed in CHEM-660-AR (DxC 660i) and CHEM-600-CH (DxC 600). Refer to the site specific QC frequency chart for QC material required.
12. Once onboard the instrument, the reagent will be stable for 14 days.
13. Record load date and expiration on UDR log.

**References:**

Microgenics DRI Tricyclics Tox Assay Application Assay Sheet 04/2009 for Beckman Coulter Synchron Systems

Thermo Scientific Infinity Lithium Reagent Assay Sheet 2013 for Beckman Coulter Synchron Systems

Microgenics DRI Ecstasy Assay Application Sheet 03/2008 Rev 3 for Beckman Coulter Synchron Systems

Stanbio Betahydroxybutyrate LiquiColor Procedure No. B2440

|  |  |  |
| --- | --- | --- |
|  | **Signature Date** | |
| **Medical Director Approval** –  ARMC Cancer Center ARMC Main Lab |  |  |
| **Medical Director Approval –** MedCenter Mebane |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Review Date** | **Signature** | **Mgmt.** | **Director** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**SOP HISTORY PAGE**

**SOP Number:** CHEM-460-AR

SOP Title: Beckman User Defined Reagent (UDR) Operating Procedure

**Written By:** Ryan Lineberry

**Manual in which Hard Copy of this SOP is located:** Chemistry

**Distribution:** None

**Supersedes Procedure:**

**SOP CHANGE CONTROL**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Approvals** | |  | **Action** | **In** |
| **Mgmt.** | **Date** | **Director** | **Date** |  | **Effect** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **Date archived: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | |  |
| **Reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Initials:\_\_\_\_\_\_\_\_\_\_** | | | | |  |