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| Dept. | CHEMISTRY | Policy #: | 04-000 |
| Policy/ProcedureTitle | BECKMAN COULTER / UniCel DxC 800 – operational overview | Effective Date: | 05/13/16 |
| Revised Date: |  |
| AuthorizedApproval: | Cindy Schwartz, CLSArea Lab ManagerJana Pindur M.D., Laboratory Director  |
| Personnel Covered: | All Chemistry Staff |
| Page: | 1 | of | 7 |

1. **PRINCIPLE**

The UniCel® DxC Synchron® Clinical Systems are fully automated, computer-controlled clinical chemistry analyzers designed for the in vitro determination of a variety of general chemistries, therapeutic drugs, and other chemistries. Analysis can be performed on serum, plasma, urine, or cerebrospinal fluid (CSF), and body fluids. See P&P 04-008 for DxC specific test attributes for acceptable sample types for each analyte.

The optical system of DxC Synchron® enables rate, endpoint, and nonlinear analysis to be performed simultaneously. These analysis are referred to as cartridge chemistries (CC) because the reagents are stored in cartridges housed in the reagent carousel. The cartridges are divided into three compartments so that reactions requiring more than one reagent can be accommodated. These cartridge chemistries can be accessed by the system in a random access manner.

Some of the more commonly ordered, higher volume analytes are performed in parallel by the DxC system. Discrete cup modules located on the left side of the system perform glucose, BUN/UREA, creatinine, phosphorus, albumin, and total protein. Analysis of sodium, potassium, chloride, carbon dioxide, and total calcium is performed in flow cell module by using electrodes specific for each analyte.

 **REQUIRED MANUALS/GUIDES**

1. Beckman Coulter Unicel® DxC Synchron Reference Manual part number A94067.
2. Beckman Coulter Unicel® DxC Synchron Chemistry Information Manual part number A45586.

***\*Note****: The operator must refer to these manuals at all times*. *Manuals can be found at* [*www.beckmancoulter.com*](http://www.beckmancoulter.com) *and in the onboard IFU.*

1. **SPECIMEN**
2. Minimum Specimen Required:  Approximately 300 L of serum/plasma/CSF and urine is required to fill the micro sample cup or tube. Depending upon the test ordered, each test requires a cup dead space of 100 L plus either 10 or 11 L of sample for each test ordered.
3. Specimen Considerations:
* Gross lipemia, icterus and hemolysis can interfere with some chemistry tests (Refer to Serum Index table). Grossly lipemic samples can be sent to Kaiser Anaheim Medical Center for ultra-centrifugation and testing.

* Samples are to be free of fibrin, cells and any other suspended particulate matter. For detailed information on specimen requirements for a specific test, refer to the appropriate chemistry test procedure.
* Frozen specimens should be thawed only once.
* After testing, the specimens should be stored at the appropriate temperature.
* The sample aliquots should have a proper label with similar information as the one on the primary collection containers.
* Specimens to be discarded should be placed in the correct biohazard container
1. **REAGENTS**

 Water Requirements: Type II deionized water.

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|  | Type II |
| Maximum microbial content (CFU/mL) | 10 |
| Minimum resistivity (megohm-cm) | 10 |
| Maximum silicate content (mg/L SiO2) | 0.1 |
| Particular matter | N/A |

1. Refer to the Reagent Inserts available at www.beckmancoulter.com for more details
2. Must adhere to the manufacturer’s guidelines and directions for reconstituting, preparing and storing reagents. Expired reagents may **NOT** be used.
3. Reagent can be loaded while system is running.
4. All new reagents required to prepare (ALT, AST, CK, LDH) must verify its performance by checking against routine controls (2).
5. The bar code includes: Reagent type, lot number, expiration date, and serial number. This allows reagent tracking for onboard stability and calibration status.
6. Reagent can be loaded manually by entering the data printed on the bar code.
7. For reagent with multiple components use components of reagent kits only within the kit lot.

**NOTE:**

1. *Remember remove screw caps from Cartridge Chemistry before loaded.*
2. *Check reagents for bubbles, clean cartridge with cotton applicators or wooden sticks.*
3. *Only mix reagents requiring special preparation.*

**Warnings and Precautions**

1. For *in vitro* diagnostic use.
2. Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination.
3. **QUALITY CONTROL**

* QC must be done at least once a day for all chemistry. **Note: OCI laboratory will run QC for all ISE tests three times a day or once per shift.**
* Controls must be run with each new calibration curve and new reagents that required preparation, such as AST, ALT, CK, LDH to verify reagent performance, or after specific maintenance or troubleshooting.
* Control limits have been pre-established. The means and standard deviations are reviewed weekly and recalculated monthly, if appropriate, by manager or designee.
* Monthly surveillance of Quality Control results are performed by the manager or designee who must review, date and initial the appropriate logs.

##### Control Guidelines/Specifications

 The technologist or manager determines whether or not the analyzer is in control.

 A run is considered out of control when any of the following occurs:

1. F3 code on one control, >3 SD from the mean (suggests random error).
2. F2 code on one control, >2 SD from the mean in two successive runs (suggests systematic error).
3. F2 code on two controls, each >2 SD from the mean in one run (suggests systematic error).
4. Patient results appear unlikely regardless of control results. Check previous results when they are available.
* The manager or designee will review data for shift and trend weekly.
* **Corrective Action**

Corrective action must be taken when controls are out. Indicate the corrective action in the daily quality control audit sheet.

**Special Consideration**

* If the run is still “**out of control**” the test should be run on the alternate analyzer and manager should be notified.
* Patient results must not be reported until QC results are acceptable. See Chemistry P&P 02-030.
1. **TEST PROCEDURE**

A. DAILY STARTUP:

1. Disinfection and Clean the counter tops/work areas.
2. Start the system
3. Check Reagent Status. Load reagent as necessary.
4. Check calibration. Program or load calibrators as needed.
5. Program or load controls, if required.
6. If the system is not already running, press the **RUN** button on the system.
7. Check the control results to verify system operation.
8. Program or load patient samples.
9. Press the **RUN** button on the system.
10. Review the patient results.
11. Return to Step 7 if more samples need to be run.
12. The system will automatically return to *Standby* when all testing has been completed.

 B. SAMPLE DILUTION:

* Samples with activities exceeding the high end of the analytical range should be rerun with \*ORDAC enabled or dilution if allowed for the analyte.
	+ \*ORDAC – *Automatic Overrange Detection and Correction: When a chemistry result exceeds the instrument analytical range and Auto ORDAC is enabled, the sample will automatically rerun with either a smaller sample size or an on-line sample dilution. Results outside this range will be suppressed. The suppressed results will be flagged OIR HI or OIR LO (****O****ut of* ***I****nstrument* ***R****ange). Refer to the Operations Manual for more details on this function*.
* Manual Dilution:
* Refer to Chemistry P&P 01-100 for dilution table guidelines.
* Refer to SGPMG QMS-0024 “Manual Dilution Policy” for guidelines regarding tests eligible for dilution.
* SYNCHRON DxC® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming

 C. CALIBRATION:

The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure.

Running Controls:

Immediately following calibration, run two levels of controls.

A calibration may be considered verified if the analyzer has reported no calibration errors and the results of the controls are acceptable in accordance to the guidelines described above.

* + If calibration fails or QC is unacceptable, repeat the calibration and QC and/or notify the manager. Patient testing may not resume for the failed analyte until both calibration and QC are successful.

**NOTE:**

1) Verify there are no bubbles in calibrator cups/tubes.

2) Calibrators should be loaded in the pre-assigned and barcoded racks.

3) Calibration (s) can be performed in the same run as controls and patients.

4) Parameters for the lot numbers of the calibrator (s) in use must be loaded prior to requesting a calibration. These are loaded via diskette included with select calibrators.

1. MAINTENANCE/DIAGNOSTIC PROCEDURE:
* Refer to the Unicel® DxC 800 Reference Manual part number A94067 for the complete operating instructions on the Unicel® DxC 800 System.
* Preventive Maintenance of Unicel® DxC 800 instructions can be found in the onboard IFU.
* The bench assigned technologists must perform the scheduled maintenance of Unicel® DxC 800 to ensure reliable system performance and document on the “Maintenance Log” by dating and initialing each of the required schedule maintenance procedure.

 F. TROUBLESHOOTING:

1. How to Home the Unicel® DxC 800:
* Press [STOP] BUTTON
* Select the instrument [COMMAND ICON]
* Select <1> Home
* System will return to “Standby” state in 5 minutes.
1. How to Power Down the Unicel® DxC 800:
* With the system standby
* Select the instrument [COMMAND ICON]
* Select <4> SHUTDOWN.
* The following message appears on the screen “This will shut down instrument and console operation”, “ Continue shutdown” [OK] [ CANCEL]. Select [OK].
* When the following message appears on the screen “System Halt.”
* Power down the Computer
* Power down Analyzer using Main Switch behind lower right hand door.
1. How to Power UP the Unicel® DxC 800:
* Power on Analyzer using Main Switch behind lower right hand door.
* Power on Computer. System will automatically Reboot – 10 min.

4. If the equipment is “**down**” tests should be run on the alternate analyzer or sent out for testing. Options are to send to Regional Reference Lab or another Kaiser Medical Center that performs the test. The floors and manager should be notified and documented in the endorsement and/or corrective action log.

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1. **REFERENCE**

Beckman Unicel® DxC 800 Clinical System Operations Manual onboard IFU.

 Chemistry P&P 02-030 “General Chemistry Quality Control”

 [www.beckmancoulter.com](http://www.beckmancoulter.com)

**Document History Page**

**Effective Date:**

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| **Change type: New, Major, Minor etc.** | **Changes Made to SOP - describe** | **Signature responsible person/date** | **Med. Director Authorized****Reviewed/Date** | **Operational Director Authorized****Reviewed/Date** | **Date change Implemented** |
| Major | New Procedure | Cindy Schwartz 5/13/16 |  |  |  |
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