TITLE: BECKMAN UniCel DxC 660i Integrated Workstation

Basic Operating Procedure

**PRINCIPLE / PUROSE:** The Beckman Unicel DxC 660i Integrated Workstation is a fully automated instrument designed for in vitro diagnostic quantitation of biological fluid components and therapeutic drugs as well as the qualitative determination of drugs of abuse in urine. The analyzer is comprised of three main sections:

* DxC – Contains (CC) Cartridge Chemistry and (MC) Modular Chemistry sections: All general chemistry including ISE.
* DxI – Immunoassay analyzer: Chemiluminescent assay’s including thyroid, hormones, cardiac and cancer markers
* CTA – Closed Tube Aliquotter for sample handling

***IFU: Instructions for use***

The Beckman Coulter IFU onboard help guide is a comprehensive instruction manual for the majority of tasks that will be performed by laboratory staff on a daily basis. The IFU can be accessed by clicking, or using the touch screen to select the question mark (?) in the upper right hand corner of the main console.

**Scope:** This procedure is a basic operating guide for technologists and technicians performing testing on the Beckman UniCel DxC 660i integrated workstation.

**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.
* Anti-Static electricity wrist strap for applicable maintenance

**SPECIMEN:**

**Type:** See Cone Health Clinical Chemistry Information Sheet (CCIS) for preferred specimen for each analyte or panel. The following are approved specimen types for each analyzer section:

**DxC 660i:** Serum/Plasma, Whole blood,Urine, CSF, Peritoneal, Pleural, JP-Drains

**DxI:** Serum/Plasma

1. ***Minimum Sample Volume Requirements:***

To determine sample volume sufficiency, compare specimen tubes to the UCTA Primary Tube Sample Template. For specimens with less than adequate volume, consider using one of the low volume options such as 0.5 mL sample cup or nesting low volume cups.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sample Cup | | **ISE**  (lytes-Any/All) | DxC | |
|  | Dead Space | Total Vol. | Dead Space | Sample/Vol. |
| 0.5 mL : Serum/Plasma | 40 uL | 120 uL | 40 uL | \* |
| Microtube : Urine | 60 uL | 140 uL | 60 uL | \* |

1. ***Interfering Substances:*** Specimens are centrifuged and the serum or plasma is separated from the cells. For hemolysis or lipemia interference, see the individual analyte procedure or CCIS for guidance. Urine samples should also be centrifuged prior to analysis regardless of clarity, including urine drug screens and urine chemistry.
2. ***Stability:*** See Beckman Unicel “DxC Systems Chemistry Information Sheets” for specimen stability specifics on each analyte.
3. ***Specimen Rejection:*** The pre-analytical integrity of all specimens submitted for laboratory testing must be assured. Pre-analytical factors include positive patient and specimen ID, absence of interferences, appropriate sample quantity, correct container, and timely receipt of specimen. A specimen may be rejected in the following scenarios (NOT all inclusive):

|  |  |
| --- | --- |
| **Rejection criteria** | **Reason** |
| Specimen NOT labeled | Identity of the patient can NOT be assured |
| Mismatched patient name with addressograph and/or barcode label | Identity of the patient can NOT be assured |
| Hemolysis – caused by collection | Results in false increases (potassium) |
| Blood collected ABOVE an infusing IV line | IV fluid contamination of blood sample |
| Specimens that leak into the transport bag | Contaminated specimen |
| Short sample | Quantity NOT sufficient to perform test |
| Specimens with needle attached | Unsafe practice for collector and lab staff |
| Incorrect collection tube used | Invalid test results |
| Excessive lag time between specimen collection and specimen receipt. | Specimen integrity compromised, invalid test results |

**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” for assay methodology and clinical significance.

See Specific procedures for user-defined assay information if applicable.

**Independent Operation:** The DxC 660i can be operated as independent instrumentation if technical issues arise. For detailed instructions on operating the analyzer’s independently see:

IFU → Contents → Chapter 9 Independent Mode

**REAGENTS:**

***Reagent Preparation:***

## See assay specific Beckman “DxC Systems Chemistry Information Sheets” for reagent preparation procedures and storage.

See assay specific Beckman “DxC Systems Chemistry Information Sheets” for information on storage, stability, safety, and content information of each reagent cartridge.

***To Perform a Reagent Load:***

## Modular Chemistries

When a MC reagent is loaded, the system assumes that the reagent is new and automatically sets the volume to 100% and the on board stability to the maximum for the reagent (see specific method sheets for actual stabilities). Some reagents may require pretreatment before placing on the instrument. Refer to the DxC chemistry information sheets for specific details.

1. Select **Rgts/Cal** from the menu bar
2. Select **<MC RGTS>** to load and/or unload any modular chemistry.
3. Select the reagent to be loaded or unloaded
4. Select **Load [F1]**
5. Open the leftmost and center doors to access modular reagents
6. Disconnect straws from fittings above cap by twisting until it can be separated by a gentle pull, and remove reagents from tray.
7. Unscrew caps, place into new reagent bottles without touching straws. (Never pool reagents)
8. Place new reagents on instrument and reattach fittings.
9. Using the hand-held bar code reader, scan the reagent bar code of the new reagent bottle. The system beeps to indicate a successful bar code read.
10. Close door and press **Done [F10]**

**Cartridge Chemistries**

Some reagents require preparation before loading onto the analyzer; refer to the specific DxC chemistry information sheets before proceeding. Remove the caps from all of the reagent compartments and remove bubbles using a wooden stick or wooden shaft swab before proceeding, a flashlight can be placed underneath the cartridge to illuminate the inside of each section to view bubbles.

1. Select **Rgts/Cal** from the menu bar
2. Select the position to be loaded or unloaded (selected positions will be highlighted).
3. Select **Load [F1]**
4. Write the date of use and your initials on the top without obscuring the barcode.
5. The instrument will prompt to remove the old reagent if necessary. To remove, grasp the cartridge from the top and bottom with the thumb and forefinger; lift slightly and pull back. The system will beep to indicate a bar code read.
6. Place the reagent to be loaded in front of the bar code reader. The system will beep to indicate a successful bar code read. Slide the reagent cartridge into the reagent carousel slot and rock slightly to ensure the reagent is in the correct position. If the bar code cannot be scanned, the reagent can be loaded manually. Once scanned, the reagent screen is updated with current reagent information.
7. To manually load reagent refer to procedure in DxC Operator Manual entitled Manually Loading Cartridge Reagents.

***Note: the following reagents should be loaded into the upper portion of the reagent carousel in positions 31-59 per Beckman Coulter recommendations: Drugs of abuse, Therapeutic Drugs, Alcohol (ETOH) and Ammonia.***

Loading a Reagent Pack on the DxI

1. System can be in any mode
2. Check the status of the reagent tray in-use light: Green – in use / Off – ready for use.
3. Write the date of use and your initials on the top without obscuring the barcode and thoroughly mix the reagent back by gentle inversion
4. Open reagent load door by lifting the bottom edge, and place up to four packs at a time onto the loading tray with the narrow end pointed towards the back with the barcode facing up.
5. Ensure the pack is flat and properly seated before closing the load door.
6. The DxI will move the pack and register it into the system through barcode scanning and place it into storage on the instrument.
7. DO NOT place partially used packs from another instrument onto the DxI as the instrument will register it as a new pack and have an inaccurate test count.
8. If loading multiple packs of the same reagent, you must perform QC on each individual pack – to do this you must only have one of the packs on PER QC run – you may need to unload packs during this scenario.

***Unloading a Reagent Pack on the DxI***

* 1. Select **Bulk Supplies** Icon.
  2. Select **Reagent Supplies (F1).**
  3. Select pack(s) to unload by using the touchscreen or mouse, up to 4 can be selected at a time.
  4. Select **Unload Reagent Pack (F2)**
  5. Wait for the screen to display the **“unload complete”** message and the green reagent tray in-use light to turn OFF.
  6. Open the reagent load door and remove the packs, close reagent load door.

***\*Important Note***

After performing a reagent load, always verify that the loaded lot # of reagent has been validated for reagent performance with first use by testing QC and patient blind duplicate. These steps must be performed before patient samples can be tested and resulted.

***Multiple Reagent Packs:***

More than one cartridge of the **same** chemistry can be loaded at one time, i.e. 2 Troponin cartridges. The analyzer will alert operator if the cartridge needs calibrating. Do not load multiple lot numbers of the same cartridge unless authorized by lab management.

***Changing an empty Substrate Bottle on the DxI***

***\*Special notes: Never force the substrate load door up, if it does not lift up easily, confirm your Rgts/Cal tab to confirm which bottle to change.***

***If the door is lifted accidentally on a partial/full bottle, then the bottle MUST BE REPLACED. When the door is lifted, any substrate left in the line will drain back into the bottle which contaminates the supply.***

1. Place a finger below the handle on the door of the corresponding empty Substrate container, apply light pressure until the door lifts automatically.
2. Push inward on the front of the load tray then release quickly, the system will release the tray outward approximately one inch, grasp by the sides and pull out gently
3. Lift the empty or expired bottle out of the tray and discard it.
4. Properly label the new bottle of substrate with date and initials, expiration date and place into the empty slot on the load tray with the barcode facing outwards.
5. Push in the load tray until it locks into place, the system will lower the door automatically.
6. Scan the barcode with the handheld scanner.
7. Always have one new bottle of substrate in the equilibration area at all times to be in a state of readiness. Substrate must equilibrate at room temperature for a minimum of 24 hours before being used.

***Changing the DxI Solid Waste Container***

1. System can be in any mode.
2. Open the solid waste door by pulling down on handle, slide the entire biohazard bin outwards from the instrument for easier access.
3. Seal the biohazard bag lining the container by tying the two ends together.
4. Remove the full bag and place into an appropriate container for disposal.
5. Line the bin with a new biohazard bag and ensure it is fully expanded so that it reaches around the edge of the entire bin. Slide the container back into the compartment.
6. **Press the green reset button located on the left side of the solid waste area to reset the system indicators.**
7. Close the lid of the waste door.

***Changing an Empty Bulk Wash Buffer Container on the DxI***

***Either a weight sensor or float sensor will monitor Wash Buffer volume.***

1. Pull out the wash buffer supply drawer.
2. Remove the perforated cardboard panels at the top and sides of a new wash buffer container.
3. Gently mix the new wash buffer container.
4. Place the new wash buffer container on the floor next to the open supply drawer and the container you are replacing.
5. Write the date of use, expiration date and your initials on the top of the container.
6. Grasp the cap on the new container and pull upward until the plastic neck is completely extended.
7. Remove the cap and inner seal of the new container.
8. Press the disconnect button to release the fitting and tubing from the cap/draw tube assembly on the empty container while gently pulling up on the fitting.
9. Lift the empty container from the supply drawer and replace it with the new container.

***\*Important Note: Avoid contaminating the wash buffer supply by not touching the draw tube with your hands or letting the draw tube touch the floor.***

1. Unscrew the cap/draw tube assembly on the empty container and carefully remove it, be sure to lift the draw tube completely out of the container before removing it.
2. Gently lower the cap/draw tube assembly into the new container (in the drawer) and tighten the cap
3. Reconnect the fitting to the cap/draw tube assembly. Carefully push the drawer back into the instrument watching to be sure the tubing does not pinched.

UCTA supplies Status

1. Select Rgt/Cal icon from menu bar at DxC monitor.
2. Select the supplies tab on the Reagent/Calibration screen to view the supply status. A supply highlighted in yellow indicates that the supply is getting low.

**CALIBRATION:**

***The performance of the analyzer is verified upon installation and after major maintenance or service to ensure that the analyzer run according to expectations with a calibration. A calibration verifies a calibration is required***:

1. Whenever a new reagent lot is used
2. A new reagent cartridge is used (except when within-lot calibration applies)
3. At recommended calibration frequency intervals
4. When indicated by control results
5. After specified maintenance and diagnostics procedures, as required by the manufacturer
6. The ISE should be calibrated every 24 hours.
7. After significant room temperature changes from the room temperature when analyte was calibrated. (See: Temperature-Sensitive Assays restricted calibration information as to affected analytes)

**DxC:**

See Beckman “DxC Systems Chemistry Information Sheets” for assay specific within lot calibration frequencies.

See Beckman Calibrator product insert for calibrator preparation, storage and stability requirements.

See Cone Health “Beckman Calibrator Chart”

***Loading a Calibrator diskette:*** Calibration parameters are calibrator-specific information as a set point or calibration acceptance limits. Some of these parameters vary from lot to lot of calibrator material and thus have a diskette that must be loaded before the calibrator is used. To load a new calibrator diskette:

From Main Menu

1. Select Rgts/Cal from the menu bar
2. Select Options [F6]
3. From the Cal Options dialog box, select <1> Load calibrator diskette
4. Insert diskette in the appropriate drive. From the Load Calibrator Diskette dialog box, select <OK>
5. Verify that the correct diskette was read based on the response on the screen.
6. When all diskettes have been loaded, select <Cancel>
7. Remove the calibrator diskette from the disk drive.
8. Calibrate affected chemistries.

***Calibration Procedure:***

1. Select **Rgts/Cal** from the menu bar.
2. Review the status to determine which chemistries need calibration. Use <**Page Down**> or **<Page up>** to view additional chemistries for calibrations. For CC chemistries only chemistries with on-board reagent are displayed.
3. Select the chemistries to be calibrated by using the touch screen or mouse.
4. Select **CAL [F4]** after all desired chemistries have been selected for calibration.
5. To review Calibrator Load List, select **List [F5]**
6. To print a load list, select **<Print>** and select **<OK>**
7. Place fresh calibrators into the appropriate calibrator racks.
8. Load the racks onto the system.
9. Press the green **RUN** on the instrument to start the calibration when ready.
10. A Calibration report will print on the printer. The instrument will alarm with any failed calibration. Review the report for any errors or messages and then perform quality control.
11. Perform quality control on the newly calibrated reagent by running the appropriate quality control material. A blind patient duplicate is required for all new lot numbers.

***Calibration failure***:

Check the following

1. Reagent dating
2. Reagent Preparation
3. DiH2O purity
4. Calibrator dating and stability
5. Incorrect calibrator used
6. Contaminated reagent or sample probes
7. Maintenance schedule

**DxI:**

Anytime the temperature fluctuate ±4ºC: FT4, BNP and CK-MB must be recalibrated.

***Adding new lot number of calibrator:***

\*Note- You must configure each new lot of calibrators before you can use them for calibration located on the box of calibrator. Otherwise select the calibrator lot number and proceed.

1. Select main menu> **Calibration (F5)** to display calibration screen.
2. Select calibrator **Setup (F5**).
3. Select Add **Calibrator (F1**). The add calibrator window is displayed.
4. Use the handheld bar code reader to scan the bar code IDs listed on the calibrator.
5. Scan the bar code ID from top to bottom. The system populates the calibrator levels, stated concentrations, and the units automatically in the table.
6. Verify the information you entered is correct and select **OK (F1).**

***Calibration procedure:***

1. From main menu select **Sample Manager (F1).**
2. Select **Calibration (F2).**
3. Select Calibrator from list. Then **OK (F1).**
4. Enter rack IDs or scan racks and press **Enter.**
5. The system enters each calibrator level in subsequent sample positions. **Load Rack X** (Open the Input lid, load racks and then close the Input lid.)

***Calibration failure***:

Check the following

1. Reagent dating
2. Reagent Preparation
3. Calibrator dating and stability
4. Incorrect calibrator used
5. Contaminated reagent or sample probes
6. Maintenance schedule

**QUALITY CONTROL:** See "QC Frequency Chart" for products used for specific controls and testing frequency.

All levels of QC on all analytes will be performed on a daily basis, as well as when a new reagent is loaded. ISE QC will be performed on each shift or every 24 hours of operation.

***\*See QC product inserts for control stability and storage directions.***

***Quality Control Run Procedure****:* Quality control specimens may be programmed on the DxC using pre-printed Bar Codes or by rack and position (Sample ID must be cleared after run). Quality control is ordered by “auto generation” by the system allowing the user to simply load the appropriate barcoded tube/rack onto the instrument. All applicable analytes will be tested by this method.

**Manually order Quality Control:**

*IFU → Contents → Program QC section → Manually program QC samples*

1. Select **Samples** from the menu bar.
2. Clear the selected ID.

* Select **Clear F7**
* Type the control ID into the Sample ID(s) field. You can enter multiple ID’s separated by commas.
* Select **OK**.
* Select **OK** to confirm.

1. Select **Control F5**
2. Select the number next to the appropriate control name.
3. Type in the rack/position number if a barcode is not available
4. Select the control ID from the pull-down menu.
5. Select Chemistries to run.

***Note:*** *For DxC only, the system automatically runs the oldest cartridge onboard for the selected chemistry. Specific cartridges (other than default) may also be selected. Select* **Rgt Cart F8** *to display available cartridges, then select the desired cartridge and select* **OK.**

1. Select **Save F10** to save the control programming and return to the Program Sample Screen
2. Load the Controls into the UCTA load tray and push the green Run button.

Using BAR CODES:

1. Place appropriate control material in the pre-printed Bar code tubes (see QC frequency chart for specific controls) in any rack and position.
2. Place rack on UCTA loading station and press green RUN button.

* Samples with bar codes require NO programming and can be placed in any rack or position. Certain racks may be designated specifically for calibrators and QC.
* Sample cups and tubes can be intermingled on a rack.

Using the Rack/position mode:

1. Select **Samples** from the menu bar
2. Enter the number of the rack and the position that the sample will be placed.
3. Select chemistries to be performed referring to QC frequency chart for appropriate control.
4. Load sample in appropriate rack and position
5. Place rack on UCTA load station and press green **RUN** button.
6. Sample ID must be cleared after run.

**OPERATING PROCEDURE:**

***General Information****:*

1. The analyzer performs direct sampling from the primary tube. Tube size will dictate which rack type should be used (13x75 / 13x100). If the serum volume is insufficient for direct sampling, the specimen may be pipetted into a nesting microcup to fit directly inside the primary tube or to a 0.5 mL sample cup nested inside of a Metal cup insert or pour off tube that has been properly labeled or programmed onto the instrument. Label the cup with sample ID or accession number, patient name and then load in the rack. Sample cups and tubes can be intermingled. Ensure that the proper rack is used for primary sample tubes with nesting cups.
2. Urine samples (timed and random) are tested in the same manner as serum samples. See site-specific addendum for calculation specifics, i.e. if performed by LIS, etc. Urine specimens should only be poured off into a validated container type (0.5mL cup or 2.0mL). **Urine and validated bodily fluids should be centrifuged before processing on the analyzer**.

***Routine Sample Programming:***

Using BAR CODES that are downloaded from Computer system:

1. Place bar-coded sample(s) in any rack and position that is not currently programmed.
2. Place rack on UCTA, DxC or DxI (DxI direct loading must have sample caps removed) load section(s) of the instrument.
3. Press green RUN button.

***Non Barcoded Sample Programming (manual programming)***

1. Select **Samples** form the menu bar.
2. Enter the number of the rack and the position that the sample will be placed.
3. Enter patient’s bar code number or other identifier.
4. Select chemistries or panels to be performed with mouse or touch screen.
5. Press **Next**.
6. Continue programming until all manual samples have been entered.
7. Load sample(s) in appropriate rack and position.
8. Place rack on UCTA, DxC or DxI load section(s) of the instrument.
9. Press green RUN button.

***For Power down / Boot / Reset instructions see:***

Main Console IFU (?) → Contents → Chapter 8 System Status, Instrument Commands and Utilities → System Shutdown/Restart

**INTERPRETING AND REPORTING RESULTS:**

***Delta Checks:*** Remisol will flag delta checks. Delta checks will be noted on the Remisol printout. Repeats will be ran by the technologist and properly documented on the Delta Check form. Recollections may be done at the discretion of the technologist or as directed by lab management.

***Reference Ranges, Critical and Call Values:***

See Cone Health CCIS for reference ranges and critical value ranges.

See Cone Health “Critical Values” list or Cone Health “Clinical Chemistry Information Sheet” for critical and call back values. Refer to procedure QM-179 “Critical Tests and Critical Values” for appropriate communication of critical values.

See Cone Health “CCIS” for analyte specific linearity (Analytical Measurement Range - AMR). Results falling outside the upper limit of the AMR must be diluted according to assay specific recommendation until the diluted value falls within the AMR. Results above the clinical reportable range (CRR) will be reported as > the CRR for that analyte. Results falling outside the lower limit will be reported as < the lower AMR value. Results that are manually diluted must include the “MDIL” canned comment for QA checking purposes.

***Reruns:***

Results may be repeated in two ways:

1. Manually programming in another cup position for only those tests that are needed.
2. Using the "RERUN"

* Select **Samples** from the menu bar
* Select **Rerun [F6]** from the Program Samples Screen
* From the Rerun Samples By dialog box, enter the desired Sample ID/Accession number to be rerun
* Select the appropriate button to request specific tests for rerun (individual tests, all tests or batch tests)
* Place rack on the UCTA load station and press RUN.

***Dilutions:***

1. Dilutions are required whenever the initial sample’s result is greater than the analytical measurement range (AMR) for a particular analyte. Instrument codes that may be observed, but are not limited to, are OIR, HIGH, and ORR HIGH. See operators manual when in doubt.
2. To perform a dilution, refer to the Clinical Chemistry Information Sheet (CCIS) to determine the appropriate diluent.
3. The dilution may be made in an appropriately labeled sample cup. The label should preferably be a computer generated label with the dilution factor written on the label. If a label is not available, then the sample can be hand labeled with the accession number of the sample and the dilution factor.
4. Place the appropriate amount of diluent in the sample cup and the appropriate sample in the cup and mix well. Dilutions must be made using the appropriate MLA pipettes to achieve the desired dilution, properly mixed and checked for bubbles before running on the instrument. Employee understanding of dilutions should be ensured before being utilized for patient testing. The smallest dilution value should be used before going to a higher dilution unless previous values indicate that a higher dilution factor is needed. Use the appropriate pipette for the dilution so that fewer aspirations are needed to achieve the desired dilution (ex: using one aspiration of a 100 uL pipette for patient sample and one aspiration of a 200 uL pipette for diluent to achieve a x3 dilution factor).
5. Program the dilution as follows:
   * + A. Select “Sample” Icon
     + Program using rack, position and B-sample id
     + Select test
     + Select “Options”
     + In the “Off-Line Dilution” field, enter the dilution factor.
6. Load the sample on the instrument
7. Verify that the diluted result is within the AMR. If it is, then report the result and attach the –MDIL canned comment. If it is still above the AMR, then repeat the dilution using a greater dilution factor.
8. Report result in the computer system, using the appropriate dilution comment.

***Fluid Chemistries (Fluids other than CSF)***

The following body fluids have been validated on the Beckman Instruments:

* Pleural Fluid
  + Glucose, Creatinine, Total Protein, Albumin, LDH
* Peritoneal Fluid
  + Glucose, Creatinine, Total Protein, Albumin, LDH

Fluids should be centrifuged and checked for clots. Clots should be resolved before placing the sample on the instrument.

Samples should be programed as a **serum/plasma** sample.

All serum analytical measurement ranges apply to fluids.

The following comment is added to all fluid chemistry results:

**“Results should be evaluated in conjunction with serum values.”**

**CSF Chemistries**

The following tests have been validated for CSF specimens on the Beckman Instruments:

* Glucose
* Micro Total Protein (M-TP)

CSF specimens should be centrifuged and checked for clots. Clots should be resolved before placing the sample on the instrument.

Samples should be programmed as a CSF sample.

CSF Glucose and Micro Total Protein have their own reference ranges. See CCIS for more information.

***Therapeutic Drug Reporting***

**Verification of samples lower than analytical range**: Samples reported out as less than the analytical range may be confirmed by diluting one part sample of known value with one part of the original patient sample. The assayed result of this dilution, when multiplied by 2, should approximate the original value of the known sample to confirm the low patient result. The confirmed result should be reported out as less than the lowest linear limit (obtained from the Clinical Chemistry Information sheet). If the assayed result of the first dilution, when multiplied by 2, does not approximate the original result of the known sample, further dilutions utilizing drug-free serum or plasma are needed.

**For the following TDM’s, confirmation (dilution/recovery studies) of results falling below the linear limit must be performed in accordance to CCIS dilution recommendations:**

**Gentamicin-“GENT”**

**Vancomycin – “VANC”**

**Digoxin – “DIG”**

**Valproic / Depakene – “VALP”**

**Do not dilute:** Acetaminophen (ACTM), Salicylate (SALI), Tegretol/Carbamazepine (TEG)

***Drugs of Abuse Screens***

Urine drug screens are used to provide qualitative results. Urine is a concentrated specimen and contains detectable drugs levels over a longer period of time than serum drug screens. Positive screens are confirmed by gas chromatography/mass spectrometry at a client’s request to avoid the possibility of a false positive result.

If the analyzer gives “AH,HR etc ….”errors for any UDS test:

-Rerun the sample

-Respin the sample and repeat on the opposite analyzer.

If the errors are still present, result the affected test with the code INTSUB “Possible interfering substance” and notify nurse.

The drugs commonly screened for are as follows:

* Amphetamines: Appears in urine within about 3 hours following oral administration. A single therapeutic dose produces positive urine tests for about 24 hours, depending on the urinary pH. High dose abusers may maintain a positive urine result through several days of abstinence. The cutoff value for a positive result is 1000 ng/mL.
* Barbiturate: The detection times for barbiturates vary greatly. Longer acting barbiturates have longer half-lives and can be detected for up to a week after administration. Phenobarbital has an extremely long half-life and can be detected for several weeks after clinical levels of seizure control. The cutoff value for a positive result is 200 ng/mL.
* Benzodiazepine: May remain detectable for 5-7 days in habitual users. Because of the large number of drugs in this group and the complexities of their metabolisms, it’s difficult to give a definite time frame of detection. The cutoff value for a positive result is 200 ng/mL.
* Cocaine: Appears in urine within 4 hours of administration. Most cocaine is excreted in the urine as benzoylecgonine, its major metabolite. It may remain detectable for up to 36 hours after a single dose. Benzoylecgonine is not stored in the body therefore even with habitual users will be negative after a few days. The cutoff value for a positive result is 300 ng/mL.
* Ecstasy: The cutoff value for a positive result is 500 ng/mL.Ecstasy is a stimulant.of the CNS. The detection times for ecstasy varies depending on several factors such as frequency, amount of drug,metabolic rate, excretion rate, drug half-life and the drug user’s age, weight, activity and diet.
* Opiates: Detectable for 24-48 hours after dose. Heroin may be detectable for up to 5 days in habitual users. Opiates refer to natural or synthetic drugs that have pharmacologic actions similar to those of opium derivatives. The cutoff value for a positive result is 300 ng/mL.
* Marijuana (THC): May remain detectable for up to 30 days in chronic users, but may be only 5 days after occasional use. Passive inhalation of marijuana smoke can result in an elevation of urine THC concentrations. The cutoff value for a positive result is 50 ng/mL.
* Methadone: May remain detectable for about 3 days. The cutoff value for a positive result is 300 ng/mL.
* Phencyclidine (PCP): The cutoff value for a positive result is 25 ng/mL. PCP is a synthetic drug with anesthetic properties. A positive urine assay for PCP generally shows use within the previous week.
* Tricyclic antidepressants: The cutoff value for a positive results is 300 ng/mL.

**CALCULATIONS:**

***Estimated Glomerular Filtration Rate (eGFR) Calculation***

The calculation used is the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. Different factors are used in the equation including gender, age and creatinine value. A different normal range will be reported based on race. This calculation will be performed automatically by the computer system on all patients 18 years and older when there is a panel that includes a serum creatinine.

The eGFR may be inaccurate in the following circumstances

* Hemodynamic instability
* Abnormal muscle mass
* Extremes of age
* Severe malnutrition
* Obesity
* Paraplegia or quadriplegia
* Pregnancy
* Medical or conditions interfering with creatinine secretion or with the creatinine assay.

The calculation used is as follows:

**eGFR = 141 x min(Scr/k, 1)a x max(Scr/k, 1)-1.209 x 0.993age [ x 1.018 if female ]**

**[ x 1.159 if African American ]**

Scr = serum creatinine

k = 0.7 (females) and 0.9 (males)

a = -0.329 (females) and -0.411 (males)

***Gap Calculation:***

***Creatinine Clearance (CRCL)***

**Specimen Processing:**

* Modify the tests under CVIS
* At the test prompt type in test exactly as it appears on the screen
* When prompted enter Total Volume
* When prompted enter Duration
* Accept modifications
* Manually enter the serum creatinine :

MEM>Test: CREA1>Acc#>Enter Serum Creatinine Value

At the online prompt on the Result Screen.

* Run Barcoded Urine sample in Gray rack with yellow overlay.
* Results should cross and LIS should calculate Creatinine Clearance.

24 hr CRCL =

***24 Hour Urine Protein (UP24)***

UP24 =

***CK Relative Index Calculation***

CK Relative Index (%) =

***Urine Protein/Creatinine Ratio (PRCRAT)***

=

**Maintenance:** The maintenance schedule should be followed per the instrument maintenance log as well as the onboard maintenance log located on the main console by touching or clicking the wrench icon at the top of the screen. Maintenance tasks that are due will be highlighted in yellow and should be completed as scheduled per your site to ensure proper instrument operation. All maintenance procedures can be found in the onboard software by clicking or touching the question mark icon **(?)** to the left of the appropriate maintenance task within the electronic log. Once completed, the operator should electronically initial on the electronic maintenance log as well as on the paper version located with each individual instrument.

ROOM TEMPERATURE ALARM:

The Access 2 system does not monitor the room temperature or alert the operator if room temperature changes from the original calibration temperature for assays identified. Quality control may not detect temperature related change in assay results and cannot be used as a substitute for temperature monitoring. Therefore; Beckman Coulter has established a restricted calibration temperature range in which the assay should be calibrated and run. Within this range, the change in assay results due to temperature is expected to be within the allowable performance characteristics of this assay. Once outside of this range, the analyte must be recalibrated.

If the room temperature chart varies outside of 20-24º

- An alarm will sound notifying techs that room temperature is out of range.

- Tech will check the temperature at which temperature-sensitive assays were originally calibrated.

-If +/- 4º change from original calibration temperature, patient testing must stop until analyte can be recalibrated.

-Tech will document new temperature at which analyte was calibrated on the Temperature Sensitive Calibration log sheet.

**\*Twice Weekly Maintenance Important Note:**

When performing the twice weekly maintenance ***“Clean Flow cell, Cups and CC Probes/Mixers”*** ensure that the system has a CCWA reagent cartridge with at least 65 tests on it to complete the maintenance procedure (you cannot use two CCWA cartridges with a total of 65 tests between them) to avoid short sampling and a delay in the procedure. If your CCWA cartridge has <65 tests, unload and discard the low reagent and replace with a new cartridge.

**TROUBLESHOOTING:** Refer to the Diagnostic and Troubleshooting Manual for aid in correcting problems.

Technical Assistance may be obtained for the Beckman Clinical Support Center at:

1-800-854-3633

For additional onboard troubleshooting help see:

IFU → Contents → Chapter 13: Troubleshooting Calibration and Result Errors

**REFERENCES:**

Beckman Coulter unicel dxi Instructions for Use (ifu) 02/2015

Beckman Coulter UNICEL DXC Instructions for Use (IFU) 03/2014

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**SOP HISTORY PAGE**

**SOP Number:** CHEM-660-AR

SOP Title: Beckman Unicel DxC 660i Integrated Workstation Basic Operating Procedure

**Written By:** Ryan Lineberry

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

**Distribution:** None

**Supersedes Procedure:**

**SOP CHANGE CONTROL**

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