TITLE: Basic Operating Procedure For beckman access 2

**PRINCIPLE / PURPOSE:** The Beckman Coulter Access 2 is an in vitro diagnostic analyzer used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.

The Beckman Coulter Access 2 immunoassay analyzer performs testing of cardiac and cancer markers, hormones and thyroid testing by use of Chemiluminescence reactions.

***IFU: Instructions for use***

The Access 2 utilizes a help menu which is also found by either touching the question mark (?) icon {F12} key on the Access workstation screen or you may refer to the IFU manual.

**SCOPE:** This procedure is a basic operating guide for technologists/technicians performing testing on Beckman Coulter Access 2 systems.

**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.

**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: Serum/Plasma

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

For specimens with less than adequate volume, consider using fhe 1 mL insert cup placed into a 13 X 75 ml tube using the required 0700 series rack.

1. ***Interfering Substances:*** Specimens are centrifuged for at least 10 minutes and the serum or plasma is separated from the cells. For hemolysis or Lipemia interference, see the individual analyte procedure. Extreme lipemic samples must be sent to Cone main lab for ultra-centrifugation for testing.
2. ***Stability:*** See Beckman Access 2 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 Access 2 Systems Information Sheets” for assay methodology and clinical significance.

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

**REAGENTS:**

***Reagent Preparation:***

## See assay specific Beckman “Access 2 Chemistry Information Sheets” for reagent preparation procedures and storage.

***To Perform a Reagent Load***

***Load Access RV’s (reaction vessels)***

* 1. Select the **RV** button from the Access workstation.
  2. Select **Load RV’s (F4).**
  3. Press the RV’s onto the spine by squeezing the top and bottom sides at the same time to ensure none are loose before opening the package ***(if a loose RV falls from the spine into the supply area when loading, service may need to be called to dislodge from the system).***
  4. Open the RV supply door.
  5. When the screen prompts you to load the RV’s open the RV load door and place the RV cartridge in the RV supply area, press down firmly on the RV load door to release the RV’s from the spine.
  6. Open the RV load door and remove the spine and verify that all vessels are present and standing upright, not protruding upward.
  7. Close the RV load and supply doors and select **Done (F1)** on the Access workstation.

***Change Access RV Waste Bag***

1. Select the RV Waste button from the Access monitor.
2. Select **Change RV Waste Bag (F6).**
3. Open the RV Supply Door
4. Unfold a new waste bag by grasping the sides and pull gently to expand it.
5. Remove the full waste bag from the instrument with a gentle upward motion (there may be an RV at the end of the chute which can be removed by hand and placed into the bag), seal the opening and discard into a red biohazard bag/bin.
6. Place the new waste bag in position by sliding the plastic collar on the bag into the slot on the waste chute. Ensure the collar is firmly seated.
7. Close the RV supply door and select **Done (F1).**

*\*Note: Access liquid waste will be disposed of in the Liquid waste bottle attached to the analyzer. As a part of daily maintenance, ensure that the waste line is in the drain and flowing properly, initial the electronic and paper maintenance logs.*

***Change Access Wash Buffer***

1. Gently invert a new bottle of wash buffer 3-4 times to mix.
2. Remove the cap and inner seal from the new bottle.
3. Remove the empty bottle and remove the dispense cap assembly.
4. Attach dispense cap assembly to the new bottle.
5. Turn the new bottle upside down and place it into the reservoir receptacle

***Loading a reagent pack on the Access***

*\*Note-**To avoid test mix up, place reagent cartridge on first then barcode/scan the reagent pack.*

1. Select the **Main Menu** or **MENU** tab from the Access workstation.
2. Select **Supplies (F3).**
3. Select **Load Reagent Pack (F1) –**Wait for the **Load Reagent Pack** window to display.
4. Mix the new un-punctured reagent pack by gently inverting to remove any particles stuck to the top (do not invert a punctured pack) and label per site requirements.
5. Open the sample carousel cover and reagent carousel door.
6. Insert the reagent pack at a downward angle and press down until it snaps into place.
7. Scan the reagent pack barcode with the handheld bar code reader and verify the system displays the reagent information on the Access workstation monitor.
8. Close the reagent carousel door and sample carousel cover.

***Unloading a reagent pack on the Access***

1. Select the **Main Menu** or **MENU** tab from the Access workstation.
2. Select **Supplies (F3).**
3. Select the pack to unload, then select **Unload Reagent Pack (F2).**
4. Wait for the system prompt to unload the pack.
5. Open the sample carousel cover and reagent carousel door.
6. Remove the reagent pack with the opposite motion of loading by pressing forward as you lift the back end of the pack.
7. Close the reagent carousel door and sample carousel cover.
8. Select **Done (F1).**

**\**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 Access 2***

***\*****Note – Access must be in READY mode to perform. Do not pop bubbles in bottle!*

1. From the Access workstation select the **Substrate** button.
2. Select **Change Substrate (F5).**
3. Scan the bar code on the new, equilibrated substrate bottle using the Access hand held bar code reader, label as indicated per site.
4. Remove the cap from the new substrate bottle.
5. Unscrew the substrate supply cap from the bottle in use and immediately place the inlet tubing and cap onto the new bottle.
6. Place the new bottle in the fluids tray, select **Done (F1).**
7. A prompt will appear asking if you want to prime the substrate, select **Yes (F1).**
8. Discard empty substrate bottle and place a new bottle onto the fluids tray to equilibrate to room temperature, label with date and time removed from refrigeration.

***\*Note – Substrate bottles must equilibrate at room temperature for a minimum of 18 hours. Note on bottle.***

**CALIBRATION:**

***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. After significant room temperature changes from the room temperature when analyte was calibrated. (See:Temperature-Sensitive Assays restricted calibration information as to affected analytes).

See Beckman “DxC/Access 2 Systems Chemistry Information Sheets” for assay specific within lot calibration frequencies.

See Beckman Calibrator product insert for calibrator preparation, storage and stability requirements. Anytime the temperature fluctuate ±4ºC CKMB must be recalibrated.

See Cone Health “Beckman Calibrator Chart”

***Access 2: Adding new lot number calibration:***

\*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 for the Access 2:***

1. From main menu select **Sample Manager (F1).**
2. Select off-board rack or enter rack ID and press **Enter.**
3. Select **Test Request (F3).**
4. Select **Request Calibration (F6).**
5. To request calibration Select calibration set **OK (F1).**
6. System enters calibration set lot number, calibrator levels, and reagent pack lot number.
7. Under Test Requests system enters each calibrator level in subsequent sample positions. **Load Rack X (F1).**
8. load Add samples to rack and rack
9. Hit **Run**

***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. .

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

**QC is unacceptable** when:

1. One control level is >3SD from the mean, or
2. Both controls are >2SD, but <3SD from the mean, or
3. One control is >2SD, but <3SD on two successive runs, or
4. Patient results appear unlikely regardless of QC results.
5. OK2L QC modifiers should not be used unless approved by lab management.

***Quality Control Run Procedure****:* Quality control specimens may be programmed on the Access 2 using rack and position.

**Manually order Quality Control:**

***ACCESS 2 Ordering Quality Control****:*

*\*note- use 0400 series Rack with the 2 mL sample Cup.*

1. From main menu select **Sample Manager,** enter the sample rack ID field and press (Enter). The rack will be displayed the Off Board test.
2. Select **Test Request (F3).**
3. Select **Request QC (F5).**
4. Select and check boxes for the required QC.
5. Select **OK (F1).**
6. Select QC test to be ordered.
7. Select **Load Rack (F4).**
8. Select **Done (F1).**

**OPERATING PROCEDURE:**

***General Information****:*

1. The Access 2 analyzer performs direct sampling from the primary tube

. (13 X 75 mm) tube. Tube size will dictate which rack type to use..

1. **Access 2 Validated Sample Containers with Racks:**

***1300 Rack***; use for lavender and green 13 x 75 mL specimen tubes.

***0700 Rack***: use for small specimen samples, place 1 mL insert tube into a 13 x 75 tube.

***2500 Rack***: use to run “calibrators” with a “0.5 mL cup”

***0400 Rack***: use to run “wash clean” and “QC” with a “2 mL cup”.

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| **Rack Icon** | **Sample Container** | **Rack Type** | **Rack Bar Code Series** | **Dead Volume (µL)** |
|  | 13 x 75 mm tube  (Light Green and Lavender) | 13 mm | 1300 to 1399 | 500 µL |
|  | 1 mL Insert Cup (P/N 81915)  In 13 x 75 tube | 13 mm | 700 to 799 | 300 µL |
|  | 0.5 mL Sample Cup  (P/N 651412) | 13 mm | 2500 to 2599 | 80 µL |
|  | 2 mL Sample Cup  (P/N 81902 or 652730) | 13 mm | 400 to 499  1 to 99 | 150 µL  150 µL |

**It is important to use the correct rack!**

Possible consequences of sample container and sample rack mismatch can be:

1. Quantity Not sufficient (QNS) error flags
2. Probe motion errors and potential pipettor damage
3. **Erroneous but believable patient results , Un-flagged short aspiration (potential wrong result)**

***Routine Sample Programming on the Access 2:***

***\*****Note: all sample caps must be removed for processing on the Access 2.*

1. From **Main Menu** Select **Sample manager (F1).**
2. Place barcoded sample tube in appropriate rack.
3. Select **Load Rack (F1).**
4. Select **Run.**

***Non Barcoded Sample Programming (manual programming) on the Access 2***

***\*Note: all sample caps must be removed for processing on the Access 2.***

1. From the **Main Menu** select **Sample Manager (F1).**
2. Enter **rack ID** number, press **Enter.**
3. Select **Test Request (F3).**
4. Enter Sample ID in appropriate position.
5. Select test(s) to run.
6. If needed, enter patient ID, Dilution factor, sample type, STAT or comment.
7. Select **Load Rack (F1).**
8. Select **Run.**

***Access 2 Shut down/reboot:***

You can reboot the PC, the instrument, or both. Rebooting either one does not affect the other.

**Shutting Down the PC Under Normal Conditions**

**NOTE :** If you are shutting down a workgroup server PC, you must shut down each of the client PCs in theworkgroup first.

**1.** Go to the PC Admin screen. To get to this screen from the Main Menu, select **Configure F8** to display the

Configure menu, then select **PC Admin F7**.

**2.** Select **Shut Down PC F8**. A confirmation message is displayed.

**3.** Select **Yes F1** to shut down the PC.

If you are preparing to shut down the server, repeat step 1 through step 3 for each of the client PCs first.

Then repeat step 1 through step 3 for the server.

**4.** Press and hold the PC power switch for at least 15 seconds to turn off the power to the PC.

**5.** Wait about 20 seconds, then perform the restarting procedure.

**Shutting Down the PC When the UI is not Accessible**

**NOTES:**

• If the server UI is the only UI that is not accessible, shut down each of the client PCs. Then use this procedure to shut down the server.

• If a client UI is not accessible, use this procedure to shut down that client PC.

• If the keyboard does not respond during the performance of this procedure, press the PC power switch on the front of the PC to turn the power off. The power switch is identified by the power switch symbol.

**1.** Take one of the following actions:

• If you know the software operating system on your Access 2 system PC, proceed to the appropriate instructions in the table below.

• To determine the software operating system on your Access 2 system PC, press the Windows® key on the computer keyboard, or press [Ctrl] + [Esc].

**Restarting a PC that Is Shut Down**

**NOTE**

If you are restarting multiple Access 2 PCs in a workgroup, restart the workgroup server first, then restart the client PCs.

**1.** Press the PC power switch on the front of the PC to turn the power on. The power switch is identified by the power switch symbol.

**2.** Wait until the Main Menu screen appears before you continue normal operation.

If rebooting fails, contact Technical Support.

**NOTE**

If communication between the PC and the instrument is interrupted for an extended time (more than 30 minutes) while the instrument is processing tests, it may take a few minutes for test results to be sent to the PC after communication is reestablished. Do not use the system until the PC receives all the test results.

Go directly to the Test Results screen and filter the results by completion time. Watch the **Result** and **Comp. Time** columns. When it appears that the test results that were obtained while communication was interrupted have been transferred to the PC, you can continue normal operation.

If you have any questions, contact Technical Support.

**Restarting the Instrument**

Use this procedure to restart the instrument from a shutdown state.

**WARNINGS**

**• You will come in contact with potentially infectious materials during this procedure. Handle and dispose of biohazard materials according to proper laboratory procedures. Proper hand, eye, and facial protection is required.**

**• Wash buffer contains ProClin™ 300 preservative, which may cause sensitization by skin contact.**

**After contact with skin, wash immediately with soap and water. Wear suitable gloves.**

**NOTE**

You must equilibrate the substrate used in this procedure to room temperature for the time specified in the reagent instructions for use before you load it onto the instrument. For detailed information, see the substrate reagent instructions for use.

**Turning the Power On**

**1.** If the PC was shut down, restart it.

**2.** Locate the power switch on the lower right side near the back of the instrument. Press the upper part of the switch to turn the power on ( | position).

**3.** Wait until the system is in the **Ready** mode and no message appears in the blue system mode area before you continue the procedure.

If initialization fails, review the Event Log and troubleshoot according to any error event with a similar date and time to the attempted initialization.

 (Optional, except following an extended shutdown) Prime the system fluidics.

 (Optional, except following an extended shutdown) Perform the probe volume checks.

 (Optional) Replenish supplies.

 (Optional, except following an extended shutdown) Run the Special Clean routine.

 (Optional, except following an extended shutdown) Run the System Check routine.

**INTERPRETING AND REPORTING RESULTS:**

***Delta Checks:*** The laboratory information system will flag delta checks. Delta checks will be noted as a comment in the LIS system. Repeats will be made if considered clinically significant by the technologist and properly documented in the LIS with applicable canned comments -RTV -DLTA etc. 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 1502 “Critical Values and STAT Results” 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.

***Dilutions:***

1. Dilutions are required whenever the initial sample’s result is greater than the analytical measurement range (AMR) for a particular analyte.
2. To perform a dilution, refer to the Clinical Chemistry Information Sheet (CCIS).
3. HCG: the analyzer will perform an automatic dilution.

See CCIS for more information.

**SUPPLEMENTAL MATERIALS / ADDENDUM:**

0371L Access II Daily Maintenance Log

**Maintenance:** The maintenance schedule should be followed per the instrument maintenance log. 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 initial the Access 2 maintenance log.

**Access 2 maintenance**: Follow Access 2 maintenance log schedule.

***Run daily clean***: to clean interior of the primary, dispense, and aspirate probes and to prime the wash buffer lines.

Prepare Rack (0400 series) by adding three, 2 mL sample cups to rack positions 1,2 and 3.

All three solutions used (Contrad, Citranox and wash buffer) are located on top left of the analyzer in cups labeled as1,2 and 3 to represent load cup positions 1,2,3.

**\*note-**Citranox cleaning solution (1 part Citranox and 4 parts DiH20) is pre-mixed and ready to use.

Position 1, pipette at least 2.0 mL of Contrad 70 cleaning solution into cup.

Position 2, pipette at least 2 mL of a 1/5 dilution of pre-prepared Citranox cleaning solution into sample cup position 2.

Position 3, pipette at least 2.0mL of wash buffer (or deionized water) into the sample cup position 3.

1. Select **Sample manager (F1)**, enter the sample **rack ID** and press **Enter**.
2. Select **Maintenance Request (F4).**
3. Select **Daily Clean System** option.
4. Select **(F1) OK**
5. Select **Load Rack (F1)**
6. When the screen displays a pop-up box containing loading instructions.

Select **Done (F1**). Select **RUN**

**Document the completion of this task on the Maintenance log**

**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:

1-800-223-0130.

**RELATED PROCEDURES:**

0369L Beckman Clinical Chemistry Information Sheet (CCIS)

0370C Beckman Coulter Calibrator Chart

**REFERENCES:**

Beckman Coulter ACCESS Clinical Systems Instructions for Use (IFU) 10/2010

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

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**SOP HISTORY PAGE**

**SOP Number:** CHEM-630-MEB

SOP Title: Beckman Access II Basic Operating Procedure

**Written By:** Terri Ernst

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

**Distribution:** None

**Supersedes Procedure:**

**SOP CHANGE CONTROL**

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