KAISER PERMANENTE

Kaiser Permanente Medical Center, San Francisco
Northern California Region
********** **********

THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION. Its use is restricted to employees with a need to know and third parties with a need to know and who have signed a non-disclosure agreement.

Work Instruction

Title: Access2 System Procedure		**WI Number** SFOWI-0023 **Revision:** 24
Department: Chemistry **Area:** 2425 Geary Blvd SFO Hospital Lab	***Approved Work Instruction***	**Implementation Date:** 07/01/2019
Type of Document: Work Instruction		**Review Period -** 365 **Days**

PURPOSE

To perform routine sample analysis of CK-MB, Troponin I (this test may be referred to as TnIA2, TnI+3 or Troponin I), β-HCG, BNP and PTH Intra-operative (PTH IO) including their calibration and quality control assays, as well as routine daily and weekly maintenance procedures, on the Beckman-Coulter Access 2 immunoassay analyzer.

PRINCIPLE

The Beckman-Coulter Access 2 analyzer utilizes immunoassays (antigen-antibody reactions) to detect or measure specific antigens or antibody (analyte) in serum or plasma. Each assay format uses reagents that react with a specific analyte to perform immune complexes. Assay reagents include an enzyme-labeled antigen or antibody (conjugate), coated paramagnetic particles and other assay-specific reagents (such as antigens or antibodies specific for the analyte being detected, stripping agents, or buffered protein solutions).

Analyte in the sample reacts with the conjugate and assay-specific reagents to create immune complexes. These complexes bind to the paramagnetic particles. A magnetic field separates the particle-bound components from the unbound components, and washing removes the unbound material from the system.

In the detection phase, a chemiluminescent substrate (Lumi-Phos 530) is added to the paramagnetic particles. The substrate reacts with the enzyme label present in the bound immune complexes and releases light. A luminometer then measures the amount of light emitted and the system converts the relative light units (RLUs) into a sample test result.

Specimen Requirements Table					
Assay (Access 2 name)	Specimen type	Centrifuged	Unacceptable specimens	Minimum sample volume (µL) required (using 2.0mL sample cup only)	Stability of Separated Serum or Plasma
CK-MB	Plasma from Lithium Heparin	As Soon As Possible	TRIG >3000 mg/dL Hemolyzed >500 mg/dL Icteric>10 mg/dL Turbid - no fibrin or cellular matter	55 uL + 150uL dead space	Room Temp.: 8 hrs 2-8 ° C: 48 hrs -20 ° C : Until tested, thaw only once
Troponin I (TnIA2)	Serum from Rapid Serum tube (RST)	ASAP; Within 2 hours of collection. Spin sample on gel barrier only once.	TRIG >3000 mg/dL Hemolyzed >500 mg/dL Icteric >40 mg/dL Turbid – no fibrin and cellular matter Tube should be no less than ½ full.	55 uL + 150uL dead space	Room Temp.: 2 hrs 2-8 °C: 24 hrs -20 °C : 6 months, thaw only once
β-HCG (HCG5)	Plain Red or SST	As soon as Possible	TRIG >3000 mg/dL Hemolyzed >500 mg/dL Icteric >40 mg/dL Turbid – no fibrin and cellular matter	25 uL + 150uL dead space	Room Temp: 8 hrs 2-8 °C: 48 hrs -20 °C : 6 months; thaw only once
BNP	EDTA Plasma	As Soon As Possible; Within 7 hours of collection.	TRIG >3000 mg/dL Hemolyzed >500 mg/dL Icteric >20 mg/dL Turbid – no fibrin and cellular matter	55 uL + 150uL dead space	Room Temp: 8 hrs Refrigerated: 24 hrs -20 °C : Until tested, thaw only once
PTH IO	EDTA Plasma	As Soon As Possible (Should be Centrifuged and refrigerated within 2 hours	TRIG >3000 mg/dL Hemolyzed >500 mg/dL Icteric > 20 mg/dL Turbid – no fibrin and cellular matter	55 uL + 150uL dead space	Room Temp.: 8 hrs 2-8 °C: 48 hrs -20 °C : 6 months, thaw no more than three times. Serum has different storage requirement. Do not use Serum.

Note: All stored samples must be tightly capped.

EQUIPMENT

1. Beckman Coulter Access 2 analyzer
2. Access 2 printer or compatible
3. Access 2 Sample Trays and/or Access 2 sample cups

REAGENTS/SUPPLIES

1. Wash buffer
2. Lumi-Phos 530 substrate
3. Reaction Vessels (RV)
4. Liquid waste bottle
5. RV waste bag
6. Calibrators and Quality Control
7. Assay Reagent packs:

Note: All reagent packs (even opened) are stable until expiration but assay needs to be recalibrated after the specified days of initial use.

a. Access CK-MB Reagent Pack

Provided ready to use. Store upright and refrigerate at 2º-10ºC. Refrigerate new shipment at 2º-10ºC for a minimum of two hours before use on the instrument. Stable until the expiration date on the label when stored at 2º-10ºC (unopened) or for 56 days (opened) after initial use. Signs of possible deterioration are a broken elastomeric layer (plastic seal) on the pack or control values out of range. If the reagent pack is damaged (i.e. broken elastomer), discard the pack.

b. Access AccuTnIA2 Reagent Pack

Provided ready to use. Store upright and refrigerate at 2º-10ºC. Refrigerate new shipment at 2º-10ºC for a minimum of two hours before use on the instrument. Stable until the expiration date on the label when stored at 2º-10ºC (unopened) or for 56 days (opened) after initial use. Signs of possible deterioration are a broken elastomeric layer (plastic seal) on the pack or control values out of range. If the reagent pack is damaged (i.e. broken elastomer), discard the pack.

c. Access Total β-HCG(5^{th} IS) Reagent Pack

Provided ready to use. Store upright and refrigerate at 2º-10ºC. Refrigerate new shipment at 2º-10ºC for a minimum of two hours before use on the instrument. Stable until the expiration date on the label when stored at 2º-10ºC (unopened) or for 28 days (opened) after initial use. Signs of possible deterioration are a broken elastomeric layer (plastic seal) on the pack or control values out of range. If the reagent pack is damaged (i.e. broken elastomer), discard the pack.

d. Triage BNP Reagent Pack

Provided ready to use. Store upright and refrigerate at 2º-10ºC. Refrigerate new shipment at 2º-10ºC for a minimum of two hours before use on the instrument. Stable until the expiration date stated on the label when stored unopened at 2º-10ºC. Stable at 2º-10ºC for 28 days (opened) after initial use. Signs of possible deterioration are a broken

elastomeric layer on the pack or control values out of range. If the reagent pack is damaged (i.e., broken elastomer), discard the pack.

e. Access Intact PTH Reagent Pack

Provided ready to use. Store upright and refrigerate at 2º-10ºC. Refrigerate new shipment at 2º-10ºC for a minimum of two hours before use on the instrument. Stable until the expiration date on the label when stored at 2º-10ºC (unopened) or for 28 days (opened) after initial use. Signs of possible deterioration are a broken elastomeric layer (plastic seal) on the pack or control values out of range. If the reagent pack is damaged (i.e. broken elastomer), discard the pack.

Note: Intact PTH reagent pack may be used for both Routine and Intra operative mode. At San Francisco laboratory this pack is used in Intra operative mode.

PROCEDURES

A. DAILY MAINTENANCE

Supplies Required:

- Fiber-free polyester swabs (or equivalent fiber-free applicators)
- Maintenance Log
- 3 mm rack for 2.0mL sample cups; the rack must have a rack ID between #1-57 or #400-456.
- Wash buffer (or de-ionized water)
- Citranox cleaning solution

Caution: Wear eye protection! Citranox cleaning solution is acidic and may cause eye and skin irritation. See manufacturer's label or MSDS for details.

Note: A 1:5 dilution of *working* Citranox cleaning solution is needed to perform the daily cleaning (see Running the Daily Clean System procedure below).The 1:5 dil Citranox cleaning solution is good for 1 week. Prepare fresh 1:5 dil Citranox solution when doing the weekly maintenance.

- Contrad 70 cleaning solution

Caution: Wear eye protection! Contrad 70 cleaning solution is alkaline and may cause severe eye irritation or mild skin irritation. See the manufacturer's label or MSDS for details.

Note: Remember to mark the appropriate box in the Maintenance Log after completing each maintenance task and write in your initials after completing all required maintenance.

1) Check Zone Temperatures

a) From the Main Menu screen select Maintenance Review [F6].
b) Verify that the temperatures (ºC) in the Zone Temperature fields are within their expected ranges (see Fig.1 below).
c) Out-of-range temperatures are displayed in red. If a temperature is out of range, call Technical Support for assistance.

Zone Expected Results	Temperature °C
Incubator	36.13-36.73
Wash Carousel	36.23-36.63
Substrate	36.23-36.63
Refrigerator	1-5

Fig.1

2) Check the System Supplies

a) Do a visual inspection of wash buffer. Determine if wash buffer requires replenishing.
b) From the Main Menu screen, select **Supplies [F3]** to display the Supplies screen.

3) Check the Wash Buffer Bottle reservoir

 Wash Buffer Icon	Replace wash buffer bottle as needed at any time. If reservoir is empty, no tests can be scheduled.

To replace bottle:

a) Gently invert a new wash buffer bottle 3 or 4 times.
b) Remove cap and inner seal from the new bottle.
c) Remove empty bottle from wash buffer reservoir.
d) Remove the dispense cap assembly from the empty bottle and attach to new bottle. Avoid contaminating bottle or reservoir.
e) Turn new bottle upside down and place into wash buffer reservoir receptacle.
f) Date and initial the bottle.

4) Check the Substrate Bottle

 Substrate Icon	● The substrate icon will display in YELLOW when fewer than 60 tests are remaining or when the substrate is within three (3) days of expiration. ● If empty or expired, the substrate button icon will display in RED. ● An extra bottle of substrate is kept in the substrate supply section on the instrument, ready to use, and is replaced each time the substrate is replaced. ● Allow **18 hours** minimum (14 days maximum) for the substrate bottle from the refrigerator to equilibrate at room temperature. ● The substrate can only be changed when the system is in READY status.

To replace the substrate bottle:

a) Press the Substrate icon (from the top of any screen) or at the Main Menu select **Supplies [F3]** to go to the Supplies screen.
b) Select **Change Substrate [F5]**.
c) Scan the new, equilibrated substrate bottle and replace old bottle with new bottle.
   - o Do not combine partial bottles of substrate when changing the substrate bottle.
   - o Keep tightly closed at all times; substrate is sensitive to air exposure.
   - o Avoid contaminating substrate bottle contents or the substrate siphon cap assembly. Contamination of the substrate may cause erroneous results!
e) Touch "Done"
f) The system will prompt, "Prime System?". Select YES.

Caution: Wear only powder-free gloves when changing the substrate bottle.

5) Check RV Supply and Load Reaction Vessels (RVs) as needed

 RV Icon	The system can hold three full cartridges or 294 RVs . Each cartridge contains 98 RVs. **Do Not** allow RVs to go below 28, as this may result in RV jams. Two rows (14 RVs per row) are required for alignment. ● When there are 60 or fewer RVs available, the RV button turns

	YELLOW. ● When there are 28 or fewer RVs available, the RV button turns RED ● If no RVs available, the system cannot process another sampleuntil new RVs are loaded onto the instrument. RVs can be loaded at any time.

To add RVs:

a) From any screen select the RV icon or from the Main Menu select **Supplies [F3]** to go to the Supplies screen.
b) When loading RVs, the whole tray has to be loaded. DO NOT leave any RV out.
c) Select **Load RVs [F4]**. Follow the system prompts to load RVs.
Caution: Remove the empty cartridge spine to prevent damage to the RV rake when loading RVs.
d) Select **Done [F1]** when task is complete.

6) Change the RV waste bag as necessary

 RV Waste Bag Icon	**Note:** The bag can hold a maximum of 300 used RVs. The number displayed counts *down* spaces remaining in the RV waste bag. ● When the waste bag has room for 60 or fewer RVs the RV Waste Bag button turns Yellow. (YELLOW). ● When the waste bag is full, the button turns RED and the system will not start processing samples.

To change the RV waste bag:

a) Check that the system is in "**Ready**" status.
b) From any screen select the RV Waste Bag icon or from the Main Menu select **Supplies [F3]** to go to the Supplies screen.
c) Select **Change RV Waste Bag [F6]**.
d) Open the supplies door at the front of the instrument, unfold and expand the new waste bag.
e) Do not push the RV that is sticking out from the ejection chute back into the chute. Instead, remove the RV.
f) Insert new bag and close the supplies door.
g) Select **Done [F1]** when task is completed.

7) Check Reagent Pack Supply

 Supplies	When an on-board reagent pack does not contain enough reagent to process requested tests, the system assigns those tests and the **Supplies Required** button turns Yellow. Reagent packs can be loaded from the Supplies Required screen, **Reagent Inventory [F7]** screen, or from the Main Menu.

Needed Icon	

To replenish reagent pack supplies:

a) Select the **Supplies Required** icon or from the Main Menu, select **Supplies [F3]**.
b) Select **Load Reagent Pack [F1]**. Open the reagent pack carousel hatch.
c) Prior to loading an unopened reagent pack, gently invert the pack a few times (5-10), in case some magnetic particles are adhering to the sides of the well or to the top of the elastomeric cover. It is not necessary to completely dislodge the button at the bottom. *Do not invert or mix an opened reagent pack.*
d) Wait and follow the message on the screen. (ie. do not insert the reagent pack before the screen shows the message)
e) Insert new reagent pack into the refrigerated reagent pack carousel at an angle, forward into the slot and then setting the back end of the reagent pack down until it clicks in place.
f) Scan the new reagent pack barcode with the barcode scanner.
g) Close the reagent pack carousel hatch and select **Done [F1]**.
h) Make sure to run QC on the new reagent pack.

8) Checking the System Backup Performed on Day and Evening shifts.
a) From the Main Menu screen select **Configure [F8]**. Then select **PC Admin [F7]**.
b) Verify that the system backup was successful.
c) Press the escape key **[ESC]** when done to return to the Main Menu.

9) System Backup Scheduled to automatically run at 1 am and 2 am. To perform a manual backup, follow instructions below.
a) The system must be in **Ready** mode to perform Backup
b) Verify that a flash drive is in the USB at the back of the computer
c) Select **Menu - Configure [F8] - PC Admin [F7] - Immediate Backup [F2]**
   - A window will open, prompting for a password. Enter: **Access2Admin**
   - Another window will open to confirm backup request. Select **Yes [F1]**
d) Backup will begin and progress for 5-10 minutes
e) When complete, a message will display, "Backup Successful". Select **OK [F1]**
f) If the system backup is unsuccessful:
   - Retry.
   - Restart the computer and retry.
   - Contact Tech Support

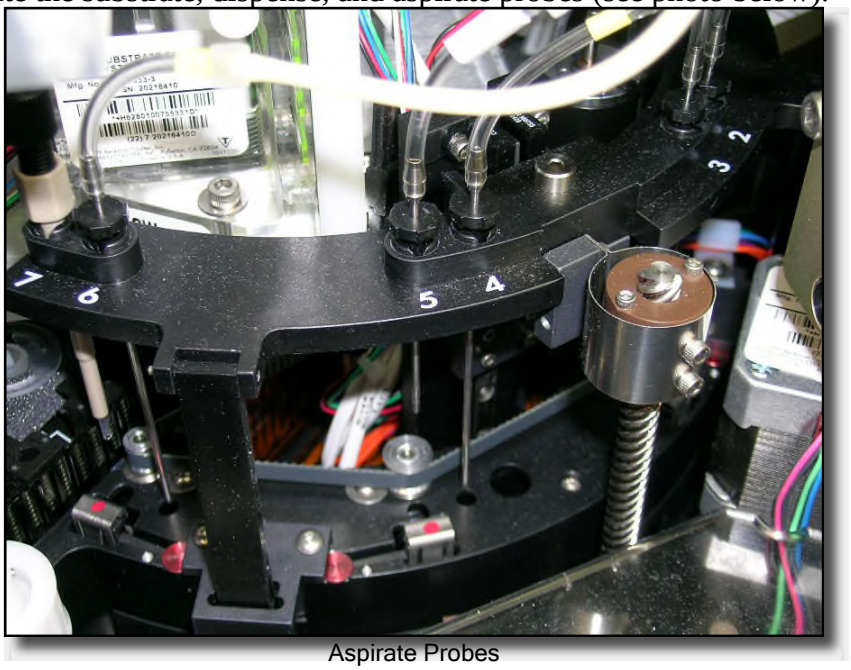
10) Inspecting the Fluidics Module
a) Be sure that the system is in the **Ready**, **Paused**, or **Not Ready** mode.
b) Open the front and top panel of the instrument.
c) Visually inspect all accessible tubing connections, valve, and pump fittings for crystalline buildup or corrosion. If you find crystalline buildup or corrosion, call Technical Support for assistance. Deposits indicate that a connection or fitting may be leaking.

d) Close the panels of the instrument.

11) Cleaning probe exteriors

Caution! Before performing this step, the Utility Assay (a self-conditioning/cleaning function) must be disabled! The Utility Assay when enabled automatically runs every 4 hours even if the instrument covers are open and could present a hazard while performing the maintenance procedures.

a) Be sure that the system is in the **Ready**, **Paused**, or **Not Ready** mode.
b) From the Main Menu, select **Maintenance Review [F6]**.
c) Select **Disable Utility Assay [F6]** to disable the Utility Assay function.
Note: The Disable Utility Assay button will now change to **Enable Utility Assay [F6]**.
d) Open the front panel of the instrument.
e) Locate the substrate, dispense, and aspirate probes (see photo below).



Aspirate Probes

Cautions: Be sure not to bend or damage the fragile probe tips. To avoid contamination, use a new swab on each type of probe. (*You will only need 3 new swabs to clean probe exteriors.*)
Do not wipe the tip of the probes. Fibers on or inside the probes can clog the probes or valves in the fluidic module.

f) Gently wipe the exterior of the substrate probe (number #7) with a new, fiber-free polyester swab moistened with wash buffer (or de-ionized water).
g) Gently wipe the exterior of the (short) dispense probes (number #1, 3, and 5) with a new, fiber-free polyester swab moistened with wash buffer (or de-ionized water).
h) Gently wipe the exterior of the (long) aspirate probes (numbered #2, 4, and 6) with a new, fiber-free polyester swab moistened with wash buffer (or de-ionized water).

Note: *You do not need to clean the exterior of the aspirate probes (#2, 4, and 6) if you are performing weekly maintenance. Refer to Weekly Maintenance procedure.*

i) Close the front panel of the instrument.
j) Re-enable the Utility Assay function by selecting **Enable Utility Assay [F6]** in the Maintenance Review screen. The button will now change to **Disable Utility Assay [F6]**.
k) Return to the Main Menu Screen by pressing the Escape key **[Esc]** when task is complete.

11) Priming the Substrate

Priming the substrate is part of daily maintenance only when the instrument is not in regular use. When the instrument is not used for four hours, priming should be performed before testing can be performed.

Note: *Priming the substrate takes approximately 8 minutes to perform and requires 32 tests. If the substrate inventory does not have enough tests for priming, replace the substrate with a new substrate bottle prior to performing the prime.*

a) Go to the Prime Fluidics window. To get this window from the Main Menu, be sure the system is in the **Ready** mode.
b) Select **Diagnostics [F7]** to display the Diagnostics menu.
c) Select **Prime Fluidics [F2]**.
d) Select **Substrate** box. If needed, select the **Cycles** field to change the number of times the system primes the substrate. The default setting is **4**. (Do not change this setting unless instructed to do so.)
e) Select **Start Priming [F2].** The system primes the substrate and displays messages about the progress of the routine. It will also notify the user when priming is complete.

Note: Start Priming [F2] will change to **Stop Priming [F2]**. Press **Stop Priming [F2]** in an emergency to stop priming.

Warning! Do not exit the priming window when priming substrate! Exiting the priming window by either pressing the escape key **[Esc]** or **Done [F8]** button has the same effect as pressing the **Stop Priming [F2]** key.

f) When priming is complete, select **OK [F1]**, then select **Done [F8]** key to return to the Main Menu.

12) Running the Daily Clean System

The daily clean system routine cleans the interior of the primary, dispense, and aspirate probes and primes the wash buffer lines. In addition to running this routine during daily

maintenance, this maintenance routine should also be run if the instrument will not be processing samples for an extended period of time. Once daily clean is running, the system takes approximately *15 minutes* to perform.

Note: Prior to performing the steps listed below, prepare a working solution of 1:5 diluted Citranox cleaning solution. *The working solution needs to be made fresh weekly.*

a) To make the 1:5 Citranox cleaning solution: *5.0 mL of Citranox cleaning solution + 20.0 mL of de-ionized water = 25.0 mL total.*
b) From the Main Menu, select **Sample Manager [F1]**.
c) Enter the Maintenance Rack Number in the **Rack ID** field. Then press **Enter [8]**. The new rack is displayed in the **OffBoard** list on the Sample Manager screen.
d) Select **Maintenance Request [F4]**. The Request Maintenance window is displayed over the Maintenance Requests screen and the Sample Manager Screen is no longer displayed.

e) Select the **Daily Clean System** option. Then select **OK [F1]**. The system will display the Position, requested routine, sample types, completion time, and status on the Maintenance Requests screen.

1	Place 2.0mL sample cups in rack positions 1, 2, and 3.
2	Pipette 2.0 ml of contrad 70 into cup1.
3	Pipette 2.0mL of fresh 1:5 diluted Citranox into cup 2.
4	Pipette 2.0mL of de-ionized water or wash buffer into cup 3.

f) Select **Load Rack X [F1]**. (The "**X**" represents the rack number previously entered in the Rack ID field on the Sample Manager screen.) Wait for "Load rack" screen to appear.
g) Slide open the sample carousel rack cover and load the rack onto the carousel.
h) Close sample carousel rack cover and select **Done [F1]** then press **Run**.
i) When the status bar indicates the cleaning is complete, unload rack. From the Main Menu, select **Sample Manager [F1]**.
j) In the **On Board** list, select the rack you want to unload then press **Get Selected Rack [F6]**.
k) Wait for system prompt then open sample carousel cover, unload selected rack, close carousel cover then select **Done [F1]**.
l) Select "Yes" when CLEAR RACK ? window appears.
m Select "Run" to get the equipment out of "Pause" status.

B. WEEKLY MAINTENANCE

In order to keep the Access 2 system running properly, perform weekly maintenance on a regular basis. If the instrument is not used to run assays every day, it is still important to perform weekly maintenance on schedule to ensure the instrument will be ready when needed.

Required materials for performing weekly maintenance:

- Lint-free cloth (Kim-wipes)
- De-ionized or distilled water
- Maintenance Log
- Alcohol or alcohol swabs or wipes (methanol can be substituted for cleaning the exterior of the aspirate probes)
- Clean aspirate probes (x3)
- Contrad 70 cleaning solution
- 2 plastic sample cups
- System Check solution (Solution can be used until expiry stated on bottle.)
- Aspirate Probe Cleaning Kit (Includes 3.0mL syringe, disposable aspirate probe brush, aspirate probe syringe fitting assembly consisting of a fitting and tubing)
- Disposable aspirate probe brushes
- Absorbent paper
- Wash buffer
- Spare waste filter bottle (as needed)

1) Clean the Instrument Exterior
   a) Moisten a clean, lint-free cloth (Kim-wipes) with de-ionized water (or distilled water).
   b) Wipe the exterior of the instrument with the moistened cloth.
   c) Check the appropriate box of the Maintenance Log when task is completed.

2) Cleaning the Exterior of the Primary Probe
   a) Be sure that the system is in the **Ready**, **Paused**, or **Not Ready** mode.
   b) Open the instrument's front panel.
   c) Visually inspect the tip of the primary probe. If it is bent or damaged, replace the primary probe. (A bent, damaged or dirty primary probe can lead to level sensing errors.)
   d) Inspect the upper portion of the primary probe for crystalline buildup. Use an alcohol swab or a lint-free cloth dampened with alcohol and carefully wipe ONLY the upper portion of the primary probe.
   e) Repeat the above step with D.I. Water.
   f) Mark appropriate maintenance task in the Maintenance Log when complete.

3) Replacing the Aspirate Probes

Caution: This step requires the analyzer to be powered *off* before removing the aspirate probes and replacing with clean aspirate probes. Power can be turned on after the clean aspirate probes have been installed.

   a) Be sure system is in the **Ready** Mode.
   b) Locate the power switch on the lower right side near the back of the instrument to power down the instrument.
   c) Press the lower part of the switch to turn the power off (O position).
   d) Once the instrument is powered down, open the front cover (if not open) and locate

the aspirate probes numbered 2, 4, and 6 on the front left side of the instrument.

e) Select an aspirate probe (#2, 4, or 6). At the barbed fitting, grasp and pull the aspirate probe tubing until it separates from the fitting. The tubing will stretch.
f) While supporting the wash arm from below, gently grab the black aspirate probe retainer above the wash arm. Gently push down on the retainer, then rotate it ¼ turn counter-clockwise.

Caution: Handle the aspirate probes with extreme care. The probes are fragile and will not function properly if bent.

g) Hold the probe by the black probe retainer, lift up to remove the probe from the wash arm, be careful not to bend the probe. Set aside aspirate probe on a clean gauze pad.
h) Locate a clean aspirate probe stored in the gray Access 2 Care (tool box) kit.
i) From the top of the wash arm, carefully route the clean probe down through the opening in the wash arm. Rotate the black probe retainer until the two tabs engage the slots in the wash arm.
j) While holding the probe by the black probe retainer, and supporting the wash arm from below, gently push down on the retainer and then turn ¼ turn clockwise .
k) Lift gently on the probe tubing to be sure the probe moves up and down.
l) Push the clean aspirate probe tubing onto the barbed fitting of a clean aspirate probe. Be sure that the tubing is pushed all the way to the barbed fitting collar. Be careful not to damage the barbed fitting or probe assembly.

Note: If the tubing is not flush against the collar, the wash system may be adversely affected.

m) Repeat the above steps with the remaining two aspirate probes.
n) After installing the clean aspirate probes, turn the instrument back ON. Locate the power switch button and press the upper part of the switch to turn power on (I position). The instrument will re-initialize and indicate when it is ready for use.

4) Perform the System Check

The System Check routine is performed as part of weekly maintenance (together with the Daily Clean) to verify the system's performance. During weekly maintenance, the three System Checks (washed, unwashed, and substrate) are run together and can also be run individually if required.

Make sure you have enough supply (i.e. RV, Substrate and Waste)

a) From the Main Menu, select **Sample Manager [F1]**.
b) Type the rack number in the **Rack ID** field and press **Enter [8]**.
c) Select **Maintenance Requests [F4]**. The Maintenance Request window will appear.
d) Select System Check (and Daily Clean System, if running daily maintenance) then press **OK [F1]**.
e) Place 2 mL sample cups in rack positions 7, 8, 9, and 10.

f) Dispense 2 mL *undiluted* System Check Solution into cup 7. Fill the cups all the way to top. Do not underfill or test will fail.
g) Dispense 2 mL of wash buffer into cup 8.
h) Leave cup 9 empty.
i) Dispense 2 mL of 1:501 *diluted* System Check Solution into cup 10.

Note: To make a 1:501 dilution of System Check Solution: *mix 20 uL of System Check solution with 10.0mL of Wash Buffer.*

j) Load the Daily Clean cups if performing daily maintenance (refer to Running the Daily Clean System in the Daily Maintenance procedure).
k) Select **Load Rack [F1]** when all sample cups are placed in rack and wait for "load rack" screen to appear. Load rack onto sample rack carousel and "done F1".
l) When done, select **RUN**. The system will take approximately 40 minutes to perform the system checks. When complete, print out the system check report.
m) From the Main Menu select **Maintenance Review [F6]**. Then select **System Checks [F2]** and then **System Check Data [F2]**. You may also review and print out past system check reports if needed.
n) To print out a report, select **Print [F7]**.
o) Compare the printed results with the **current** expected values listed in the Maintenance Log sheet. (See Fig.2 below for a sample of System Check Expected Results table). Also Dark count should be < 50 and drift correction should be <1.5.
p) If result(s) is out of specification, refer to section 7, "System Check troubleshooting" section 7.3-7.12 in Access 2 quick reference guide for corrective action and repeat.
q) Record the results on the maintenance log.

System Check Expected Results	
Washed Check	
RLU mean	5,000–20,000
% CV	≤ 12.00
Substrate Check	
RLU mean	5,000–9,000
% CV	≤ 5.00
Substrate ratio	0 - 1.40
Substrate : Washed Ratio	0 - 1.00*
Unwashed Check	
RLU mean	4–10 million*
% CV	≤ 2.00
Wash Efficiency	
PPM	0 - 5.00

* The Substrate : Washed Ratio and the Unwashed Check RLU mean result are not system specifications. They are only reference guidelines.

Fig. 2

5) Cleaning the Aspirate Probes

There are three steps to clean the Aspirate Probes after removing them from the analyzer for weekly maintenance: Precleaning, Cleaning with Contrad 70 cleaning solution, and Cleaning with De-ionized Water (D.I. H_20).

a) Precleaning

1	Fill a small cup or beaker with approximately 20mL of Contrad 70 cleaning solution
2	Fill another small cup or beaker with approximately 50mL of de-ionized water.
3	Dip the aspirate probe brush (located in the Care kit) in the undiluted Contrad 70 solution. Only one aspirate probe brush is required.
4	Carefully insert the aspirate probe brush into the bottom end of the aspirate probe and push it in until the brush protrudes slightly from the other end of the probe.
5	Remove the aspirate probe brush.
6	Repeat the above steps several times on the same probe, or until no orange residue is visible on the brush after removing it from the probe. Use the same cleaning brush on the remaining two probes.
7	When finished with all three aspirate probes, discard the used probe brush in a biohazard Sharps container.

b) Cleaning with Contrad 70 cleaning solution

1	Locate the plastic syringe found in the gray Care kit and fill the syringe with Contrad 70 cleaning solution.
2	Connect the syringe tubing to the aspirate probe's plastic barbed fitting. Empty the syringe by forcing the Contrad 70 cleaning solution through the aspirate probe and back into the beaker containing Contrad 70 cleaning solution or into a sink. Repeat three (3) times.
3	Disconnect the syringe tubing from the aspirate probe and repeat the steps with the remaining two (2)probes.
4	After cleaning with Contrad 70 cleaning solution, disconnect the syringe tubing. Fill the syringe with de-ionized water. Repeat the above steps using de-ionized water to flush all 3 aspirate probes.

c) Cleaning with De-ionized Water

1	Fill the syringe with de-ionized water. Repeat the above steps using *de-ionized water* instead of Contrad 70 cleaning solution to flush all three (3) aspirate probes.
2	When done, wipe all three aspirate probe exteriors with alcohol. Let probes dry upright on absorbent paper for about 10 minutes to allow residual fluid to drain.
3	Return cleaned aspirate probes and syringe into plastic storage containers and store in tool kit for the next weekly maintenance.

C. CALIBRATION

Test	Calibrator Storage	Calibrator Stability	Calibration Stability
β HCG(5th IS)	Store at -20°C	Until expiration date	28 Days
	Thaw at room temperature before use. Return to -20°C after use	Stable for 120 days after initial use or 4 freeze thaw cycles.	
BNP	Store at -20°C	Until expiration date	28 Days
	Open vial at 2-10°C	30 Days	
CK-MB	Store at 2-8°C	Until expiration date	56 Days
	Open vial at 2-10°C	60 Days	
TnIA2	Store at -20°C	Until expiration date	56 Days
	Open vial at 2-10°C	60 Days	
PTHIO	Calibrators and Reconstitution Buffer stored at 2-8°C	Until expiration date	28 Days
	Reconstituted vial stored at 2-10°C	10 hours	

Notes: a) For PTH IO calibration, reconstitute each calibrator vial volumetrically with 1.0 mL PTH Reconstitution Buffer. Allow 30 minutes for dissolution. Mix gently before use.

b) Verify that all supplies (reagents and waste) are acceptable prior to performing these steps.

c) The system will process calibration samples before quality controls

and routine samples are performed.

d) For every new lot of reagent, calibration must be performed.

Calibration Procedure

1) Check the calibrator lot number. If the calibrator lot number is in use, proceed to step 3.
2) For a new lot of calibrator, install the information as follows: Main Menu / Calibration / Calibrator Setup / Add calibrator. Follow the screen prompts to scan the barcode sheet that comes with the calibrator. When complete, select "O.K." to exit.
3) From the Main Menu screen, select **Sample Manager [F1]**.
4) Enter a rack ID number in the **Rack ID** field and press **Enter [8]**.
5) Select **Test Request [F3]**.
6) Select **Request Calibration [F6]**. The Request Calibration window will display.
7) Select the appropriate calibrator lot, then select **OK [F1]**.
   Note: The system enters each calibrator level in subsequent sample positions on the Test Request screen. The selected test and the current reagent pack lot number for that test display on the calibration view of the Test Menu.
   - To change the reagent lot for a calibration, select the calibrator set, then select **Change Reag. Lot**.
   - If the wrong calibration test was requested, select **Delete Sample [F2]**. Then return to **Request Calibration [F6]**
   - To hide the Test Menu, select **Hide Test Menu [F3]**.
8) Dispense appropriate calibration sample fluids into sample cups in the order displayed on the Test Request screen. Make sure to dispense in the correct order or calibration results will be incorrect.
   Note: Calibrators are run in duplicates for all tests except aTnI. For aTnI, the first 2 calibrators are run 4 times.
9) Select **Load Rack X [F1]**. (The "**X**" represents the rack number previously entered in the Rack ID field on the Sample Manager screen.) Wait for "load rack" screen to appear. Slide open the sample carousel rack cover and load the rack onto the carousel. Close sample carousel rack cover.
10) Select **Done [F1]** then press **Run**.
11) When complete, the calibration results will print out.
12) Fill out an Access 2 Calibration Worksheet for each calibration.
    Note: For BNP2, record the ambient temperature at the time of calibration. Use Fusion room temperature from Check-point.
13) Perform patient correlation on the new lot vs old lot of reagent.
    Note: For recal of an existing lot, 5 samples are sufficient.
    - From available samples, select 10 that span the reportable range.
    - Test with old lot and new lot of reagent.
    - Calculate the percent difference between the samples.
    - Evaluate for acceptability based on CAP limits for the test.
14) File in Access 2 calibration results binder or appropriate. If calibration results are out, investigate problem(s) and notify a supervisor.

D. QUALITY CONTROL

See "Quality Assurance Plan for Chemistry and Coagulation" (SFOWI-0218) section of the "General/Misc Procedure" binder for guidelines regarding Q.C. Document actions taken to identify and correct any instrument problems in "Supplemental Maintenance" and Q.C. problems in the "Out-of-Control" sections of the "Q.C. and Maintenance" binder for the instrument.

1) Control Products, Storage and Stability

WARNING: Human source material; treat as potentially infectious.

a) Controls by Test:

- **ß-hCG**: Bio-Rad Liquichek Immuno Assay Plus levels 1 and 3, and Bio-RadLyphochek Fertility Control Level 3
- **CK-MB**: Bio-Rad Liquichek Cardiac Markers Plus Control LT, levels 1 & 2.
- **Troponin I**: Bio-Rad Liquichek Cardiac Markers Plus Control LT, levels 1 & 2.
- **BNP**: Bio-Rad Liquichek Cardiac Markers Plus Control LT, levels 1, 2 and 3.
- **PTH IO**: Bio-Rad Liquicheck Specialty Immunoassay Control Level 1, 2, and 3.

b) All unopened control products are stable until the expiration date when stored according to manufacturer's instructions. All in-use controls require gentle mixing prior to use, to ensure homogeneity.

<table>
<tr><td colspan="5">Access Quality Control Products Handling</td></tr>
<tr><td></td><td>Bio-Rad Lyphocheck Fertility</td><td>Bio-Rad Liquichek Immunoassay Plus</td><td>Bio-Rad Liquichek Cardiac Marker Plus</td><td>Bio-Rad Liquichek Specialty Immunoassay</td></tr>
<tr><td>Stock Location</td><td>Store Room Chem Ref #1</td><td colspan="3">Revco Freezer #1</td></tr>
<tr><td>In-Use Location</td><td colspan="3">Chem Under Counter Refrigerator #1 in Access area</td><td>Revco Freezer # 1</td></tr>
<tr><td>In-Use Stability</td><td>7 days at 2-8°C.</td><td>14 days at 2-8°C.</td><td>CK-MB - 20 days
TnI - 10 days
BNP - 8 days
all at 2-8°C.</td><td>7 days at 2-8°C.
frozen aliquots for 30 days at
-20 to -70°C.</td></tr>
<tr><td colspan="5">Specific thawing/reconstitution instructions
o Bio-Rad Lyphocheck Fertility - Use a volumetric pipette to reconstitute with 5.0 mL of deionized water. Replace the stopper and allow the control to stand for 15 to 20 minutes, swirling occasionally.
o Bio-Rad Liqicheck Immunoassay Plus & Bio-Rad Liquichek Cardiac Markers Plus - Allow frozen controls to stand at room temperature until completely thawed. Once thawed, do not refreeze the control
o Bio-Rad Liquicheck Specialty Immunoassay Controls - Allow frozen controls to stand at room temperature until completely thawed. Aliquot 300 uL control into conical micro-centrifuge vials,label with aliquot labels and refreeze. Thaw as needed. Discard remaining material after thawing.</td></tr>
</table>

2) Performing Quality Control. Run controls at least once a day. Controls are also run along with each calibration and when a new reagent pack is loaded.

Note: Verify that all supplies (reagents and waste) are acceptable prior to performing these steps.

a) From the Main Menu screen, select Sample Manager [F1].
b) Enter a rack ID number in the Rack ID field and press Enter [8].
c) Select Test Request [F3]. Make sure the cursor is in the correct sample position.
d) Select Request QC [F5] to order a QC run. The Request QC screen will display available quality control samples.
e) Choose the correct QC sample(s) to run by pressing or clicking the empty box(es) on the left hand side of the Request QC screen. (Note: There may be more than 1 file for each QC). Verify that lot numbers and expiration dates match the labels on the QC sample bottles. When selected, a check mark in the box will indicate the QC samples to be run.
f) When all QC samples to be run have been chosen, select OK [F1]. The Test Request Screen will then display the QC samples on the chosen rack.
g) For each QC sample, select test(s) to be run using the Test Menu.
    - If the test menu is not displayed, select Show Test Menu, F3.
    - If the wrong test was selected, highlight the test and touch Remove.
h) Place 2.0 ml sample cups in a rack appropriate for the sample container. Dispense approximately 0.5mL of appropriate QC sample per sample cup, in the order displayed on the Test Request Screen.
i) Select Load Rack X [F1]. (The “X” represents the rack number previously entered in the Rack ID field on the Sample Manager screen.) wait for "load rack" screen to appear.
j) Slide open the sample carousel rack cover and load the rack onto the carousel. Close sample carousel rack cover.
k) Select Done [F1] then press Run.
l) When complete, the QC results will print out. File in Daily QC binder or appropriate. If QC results are out, repeat QC. If QC still out, investigate problem(s) and/or notify supervisor.
m) To document out of control results:

1	Main menu F9
2	Quality control F4
3	Select the QC file that is out, (You may have to deselect the test that was last selected.)
4	Review chart and data F2
5	Select the QC data that is out
6	Hit "comment" box
7	Type in corrective action in the "QC comment window"
8	Select "F1 OK" when done.
9	The comment box will change from black pen icon to a yellow notepad icon.
10	If wrong QC was run, enter a comment and enter a check in the "Omit" box.

E. SAMPLE PROCESSING

Performing Routine Assays (Patient Samples)

Note:

1. Verify that all supplies (reagents and waste), quality control and/or calibrations are acceptable prior to performing any patient sample testing.

   Remember: Tell - Wait - Do - Done rule for this analyzer

2. Note: PTH IO is not an orderable test in Health Connect system. Manual requisition will be handed to the staff with the sample from Operation Room. The test must be ordered manually in RILIS system and results must be called to the O.R.

   Order priority : Expedite
   Test mnemonic; PTH IO
   Turn Around Time : 20 -30 minutes.

   Surgeons expect the results in 20 minutes if possible.

1) **<u>Automatic (RILIS downloaded) test request</u>**:

To automatically run specimen(s) with barcode labels, remove all specimen caps and load specimen tubes in the rack with their barcodes facing outwards. Make sure to use the appropriate sample rack for each sample tube used. Refer to the chart below:

Sample Tube with Rack and Volume Requirements for ACCESS 2

Tube Size	Rack ID	Dead Volume	Sample Pick up Size
Sample cup (Aliquot)	1-99	150 µL	TnIA2 = 55 µL CK-MB = 55 µL BNP = 55 µL PTHIO = 55 µL HCG5 = 25 µL HCG5d = 6 uL
12x75 (PST)	1300-1399	500 µL	
13x100 (RST)	1400-1499	3 mL	

If the volume of plasma/serum on tube is below the minimum volume, please use an aliquot cup.

Caution! *The Access 2 analyzer is NOT a cap-piercing analyzer!*

a) From the Main Menu screen, select **Sample Manager [F1]**.
b) Select "Load a Rack"
c) Wait for the system prompt.
d) Open specimen carousel cover and load the rack with samples. Close the carousel cover and select **Run.** The system will scan the rack and sample(s) barcodes. Tests ordered from RILIS are downloaded to the system automatically.
e) When tests are complete, unload the sample rack. From the Main Menu, select **Sample Manager [F1]**.
f) In the **On Board** list, select the rack you want to unload then press **Get Selected Rack [F6]**.
g) Wait for system prompt then open sample carousel cover, unload selected rack, close carousel cover then select **Done [F1]** and "YES" to clear the rack.
h) Stat result will be printed as it's finished.
i) Routine results will be printed when the whole page is filled up or when there are no more samples running

2) **Manual Test Request**

a) To manually order patient tests or when RILIS is down, from the Main Menu screen select **Sample Manager [F1]**.
b) Enter the rack ID number in the **Rack ID** field and press **Enter [8]**.
c) Select **Test Request [F3]**. If sample is in rack position number one, for example, highlight the **1** button on the left side of the screen.
d) Enter the sample's ID number in the Sample ID field via barcode scanner or manual keyboard entry.
e) Enter a patient name or MR# in the Patient ID field.

- If sample is a STAT specimen you can select the STAT button to prioritize a STAT specimen. If selected, a check mark (a) will appear in the box to indicate a STAT specimen.
- If a comment needs to be added to the specimen, select the comment button and the Sample Comment box will appear. Type in a comment and when done select **OK [F1]** or **Cancel [F8]** to return to the Test Request screen.

f) Uncap specimen tubes and load in rack and/or load samples in sample cups onto rack. Refer to *Specimen Requirements Table* in **Specimen** section for appropriate sample volumes.
g) Select tests to be ordered in the Test Menu inset displayed within the Test Request screen. If it is not displayed, select **Show Test Menu [F3]** in the Test Request field to display all tests that are performed on the Access 2.

- To remove the Test Menu screen inset, select **Hide Test Menu [F3]**.

h) Select the tests to be performed by pressing the appropriate assay

button in theTest Menu. At Kaiser Permanente San Francisco, our choices are: CK-MB, TnIA2 (Troponin I) or Cardiac (includes CK-MB & TnIA2), HCG5 (undiluted βHCG), HCG5d (diluted βHCG), BNP2 and PTH IO.

- To remove a test ordered for a specimen sample, highlight the test to be removed and press **REMOVE**.

  Note 1: Selected tests are displayed in the Test Menu field labeled "**Tests requested for sample 1"** (if sample 2 is being ordered, the label will read "…sample 2" and so on) or under the sample ID in blue lettering..

  Note 2: Assays can also be performed multiple times on the same test sample. For example: Pressing the CK-MB assay button 3 times will result in the assay being run 3 times. Check if sample volume is sufficient to run multiple testing prior to performing this step.

i) Highlight the next sample position button (2, 3, 4, etc.) and repeat steps 4-8 to order tests for the next sample.

- To delete samples on a rack, select the sample's position number on the rack in the Test Request screen and select **Delete Sample [F2]**.
- To clear all samples on a selected rack, select **Clear All Samples [F7]**.

j) Repeat the above steps until all patient samples have tests ordered.
k) Select **Load Rack X [F1]**. (The "**X**" represents the rack number previously entered in the Rack ID field on the Sample Manager screen.) Wait for "Load Rack" to appear.
l) Slide open the sample carousel rack cover and load the rack onto the carousel. Close sample carousel rack cover and select **Done [F1]** then press **Run**.
m) Repeat the above steps to load another sample rack.
n) Test results will automatically print out when completed.

F. ANALYTICAL MEASUREMENT RANGE AND CLINICAL REPORTABLE RANGE

Test	Analytical Measurement Range (AMR)	Clinical Reportable Range (CRR)
ß-hCG (HCG5)	0.2 - ~1300* mIU/mL	1.0 - 375,000 mIU/mL
BNP	1 - 4900 pg/mL	1 - 4500 pg/mL
CKMB	0.1 - 300 ng/mL	0.1 - 270See Reporting Result
Troponin-I (TnIA2)	0.02 - 100 ng/mL	0.02 - 90.00 ng/mL
PTH IO	6 - 3000 pg/mL	6 - 3000 pg/mL

* depends on the limit of the S5 calibrator

G. REFERENCE RANGES

1) **ß hCG:**

Sex	Age (years)	Reference Interval (mIU/mL)
Female	<41	<2
Female	41-50	<6
Female	>50	<8
Male	All	<2

2) **BNP: ≤100 pg/mL**
In evaluating patients with dyspnea, a BNP <100 pg/mL makes a diagnosis of CHF unlikely. BNP 100-300 pg/mL is consistent with CHF, but patients are usually not symptomatic at these levels. Other causes of dyspnea should therefore be considered. BNP 300-600 pg/mL is consistent with CHF or pulmonary hypertension/embolism. BNP >600 pg/mL is diagnostic of decompensated CHF.

3) **CKMB**

CKMB %= (Access 2 CKMBF / Total CK)x100
CKMB Interpretive Data:

Normal	CKMBF less than 5.6 ng/ml and CKMB% (Index) less than 3.3 ng/ml.
Abnormal	CKMBF greater than 5.6 ng/ml and CKMB % (Index) greater than 3.3 ng/ml.
Inconclusive	CKMBF greater than or equal to 5.6 ng/ml and CKMB % (Index) less than or equal to 3.3 ng/ml. OR CKMBF less than or equal to 5.6 ng/ml and CKMB % (Index) greater than or equal to 3.3 ng/ml.

4) **Troponin-I (TnIA2) : 0.00 - 0.04 ng/mL**

5) **PTH IO : No reference range**. Interpretive comment only. See below.

H. REPORTING RESULTS

1) **ß-hCG**
   a) Results less than 1.0 should be reported <1.0 mIU/mL.
   b) Results greater than ~1300 will reflex the test HCG5d and report a 200X dilution of

the sample. If the result is reported with a greater than > symbol, an additional dilution will be required.

c) Dilution Factor adjustments in the Assay Setup may result in reports of HCGd > a number other than the expected limit (determined by multiplication of 200 x high calibrator). A manual dilution is required to determine the actual value.
   - Perform a manual 1:2 dilution using Wash Buffer
   - Load the sample on the Access and request HCG5d on the sample
   - Multiply the result by your dilution factor (2)
   - If the result is >375,000, report as >375,000. If below, report the calculated value

d) ßhCG RILIS Result Verification and Interpretive Comment:

1	The results of the ß-hCG test are calculated automatically by the Access 2. The concentration of ß-hCG is displayed on the screen, as well as on a printout. Check the printout for flags and/or error codes. Any flags or error codes must be resolved prior to verifying results.
2	In RILIS, select the Cerner Millennium function ARE (Accession Result Entry)
3	Enter the accession number of a ß-hCG result to be verified.
4	Result from Access 2 will automatically load to ß-hCG result field.
5	If previous results are available, do delta check.
6	Select *Verif* to load results to patient's records. The results will be reported with an interpretive comment: Post menopausal women may have hCG concentrations up to 11 mIU/mL. The KPNC hospital laboratories use the Beckman Access to quantify hCG. Results between the Regional Laboratory and the Hospital Laboratories should not be used interchangeably when serially monitoring patients.

2) BNP

a) Results less than 1 should be reported <1 pg/mL.
b) Results greater than 4500 pg/mL should be reported > 4500 pg/mL.
c) BNP RILIS Result Verification

1	The results of the BNP Test are calculated automatically by the Access 2. The concentration of BNP is displayed on the screen, as well as on a printout. Check the printout for flags and/or error codes. Any flags or error codes must be resolved prior to verifying results.
2	In RILIS, select the Cerner Millennium function ARE (Accession Result Entry)
3	Enter the accession number of a BNP result to be verified.
4	Result from Access 2 will automatically load to BNP result field.
5	If previous results are available, do delta check.
6	Select *Verify* to load results to patient's records. The results will be reported with an interpretive comment: "In evaluating patients with dyspnea, a BNP <100 pg/mL makes a diagnosis of CHF

	unlikely. BNP 100-300 pg/mL is consistent with CHF, but patients are usually not symptomatic at these levels. Other causes of dyspnea should therefore be considered. BNP 300-600 pg/mL is conistent with CHF or pulmonary hypertension/embolism. BNP >600 pg/mL is diagnostic of decompensated CHF."

3) CKMB

a) CKMBF Results less than 0.1 should be reported <0.1 ng/mL.

b) CKMBF Results greater than 270 ng/mL:

1	If CKMB% (Index) is > 3.3, report as CKMBF > 270 ng/ml and attach Abnormal interpretive template.
2	If CKMB% (Index) is < or = 3.3, dilute sample with equal volume of CKMB diluent A. Enter sample dilution (2) in the test request field. System report results adjusted for dilution. On RILIS, look at the CKMB% (Iindex) and attach appropriate interpretive template.
3	If CKMBF result is > twice the value of highest calibrator ng/mL, after 1:2 dilution, check with supervisor to determine an appropriate dilution before proceeding, or refer to Appendix A, CK-MB Dilution Example, at the end of this procedure. ● Supervisor or In Charge CLS will look at the RLU for the high value and do a proportional analysis of the RLU for a high readable result and concentration, compared to the RLU for the sample without an endpoint (concentration) ● Solve the equation for the unknown concentration and then divide that result by 300 to get a dilution factor. ● Rerun the sample using the recommended dilution and determine CK-MB index. ● Report result with appropriate interpretive comment.

c) CKMB RILIS Result Verifcation and Result Comment:

1	Verify the CKMB result in ARE .
2	CKMBF result will be measured by the Access 2 and uploaded to the LIS.
3	CKMB % is automatically calculated by the LIS.
4	Attach an interpretive comment to the CKMB Percent result. Select *Comment* from the task bar. When the Comment window opens, make sure the tab is on Result Comment, then select *Edit.* Type in "SF_CKMBI" and function key **F9** to import the comment template. The comment will read: CK-MB Interpretation:_____. Enter either Normal, Abnormal or Inconclusive. Select *OK* and then *Close*..
5	Verify CK TOT, CKMBF and CKMB% results.

4) Troponin-I (TnIA2):

a. Results less than 0.02 should be reported <0.02 ng/mL.

b. Results greater than the highest calibrator value should be reported > 90.00 ng/mL.

c. Check specimen for clots BEFORE and AFTER running (prior to verifying). Review and verify the results if no clot is found; if a clot is present, do not verify the result.

d. Follow the workflow FCD document to improve patient care by expediting the TAT for Troponin.

d. If a clot is visible in the sample, do the following:
- Rim the sample again with the use of an applicator stick.
- Transfer the sample to an aliquot tube and re-spin the sample (micro-centrifuge); once finish, check the sample for clots.
- If no clots are found proceed with running the sample. Review results and verify.

IMPORTANT: Confirm sample integrity before verifying Troponin I samples. If a clot is found after the sample has been run, do not verify. Repeat the process and rerun the sample on the other analyzer. Review results and verify accordingly. Document steps taken in order to keep track for time management purposes. If in any circumstance the the CLS is doubtful of the TROP I result, cancel the order and request for a redraw.

e. Troponin-I RILIS Result Verification and Result Comment:

1	Select ARE from the App Bar and enter the Accession Number of a Trop I test to be verified.
2	TROP-I is a group test consisting of 3 detail tests: TROPI, TROPN, and TROPA. ● TROPI = interpretation: "Effective July 15, 2014, NCAL laboratories implemented a new cutoff for Beckman Tn-I, >0.04ng/mL (or ≥ 0.05ng/mL flag abnormal in KPHC). The diagnosis of acute myocardial infarction depends on detection of a rise and/or fall of cTn or CK-MB with at least one value above the 99th percentile upper reference limit, >0.04ng/mL, in addition to clinical or ECG findings. Elevated but unchanging troponin concentrations may be due to myocardial injury in the absence of acute coronary syndrome." The result field for this line displays as "See Note" ● TROPN = numeric value of test result. ● TROPA = "TNI BECK" for Beckman Coulter
3	Review results and previous results if available.
4	Verify TROPI, TROPN AND TROPA results.

5) PTH IO:

a) PTH IO Results less than 6 pg/mL should be reported <6.0 pg/mL.
b) PTH IO Results greater than 3000 pg/mL is reported as >3000 pg/mL
c) PTH IO RILIS Result Verification:

1	The results of the PTH IO Test are posted automatically in RILIS. The concentration of PTH IO is displayed on the screen, as well as on a printout.
2	Select ARE from the Cerner Millennium App Bar
3	Enter the accession number of a PTH IO result to be verified.

4	The PTH IO result will be displayed in the result field.
5	All PTH IO results must be called to the O.R. and documented as such.
6	Enter a Result Comment by selecting *Comment* from the task bar. ● When the Comment window opens, make sure the tab is on Result Comment. ● Select *Edit* . ● Type in "SF_RB" and function key **F9** to import the comment template. ● Fill in blanks for the comment: _:Test results phoned to and verification read-back made by _, title _, ext _, date/time _, called by _. ● Select *OK* ● Select *Close* .
7	All PTH IO results are reported with an interpretive comment that reads, " At least a 50% reduction in PTH value should be observed when the highest base line sample is compared to the post-resection samples".
8	Verify the PTH IO result.

I. INTERFERING SUBSTANCES/LIMITATION

This list is not comprehensive. Please refer to the *Beckman Coulter Access2 Assay Manual,* Assay Specific *Instructions for Use* for a complete list.

1) All assays employing antibodies are limited by the possibility of interference by **heterophile antibodies** in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA or GAMA, that interfere with immunoassays.

   a) Results from patients suspected of having heterophile antibodies should be evaluated in light of clinical presentation, patient history, and additional testing.
   b) If the total ß-hCG is inconsistent with clinical presentation, results should be confirmed by an alternate method or a urine-based assay.
   c) If TnIA2 is consistently elevated without clinical symptoms of MI, heterophile antibody may be present. An alternate method for Troponin I is the I-Stat.

2) The "Hook" Effect is a false negative result in an immunoassay, due to very high levels of analyte.

   a) ß-hCG - no demonstrable "hook" effect up to 1,000,000 mIU/mL
   b) BNP - no demonstrable "hook" effect up to 150,000 pg/mL
   c) CK-MB - no demonstrable "hook" effect up to 20,000 ng/mL
   d) TnIA2 - no demonstrable "hook" effect up to 2500 ng/mL
   e) PTH IO - no demonstrable "hook" effect up to 250,000 pg/mL

3) Automatic dilutions of serum samples HCG5d onboard dilution have the potential of generating individual results with bias > 15%. Troubleshoot the instrument when bias of 15% or greater is observed.

I. REFERENCES

1. *Beckman-Coulter Access 2 Operator's Guide* . September 2014. Part number

B14251D.

2. *Beckman-Coulter Access 2 Quick Reference Guide* . September 2014. Part number B14253C.
3. *Beckman-Coulter Access 2 Assay Manual Instructions for Use.* CK-MB, 2010; Troponin-I (aTnI+3)2013; Intact PTH 2011, Total β-HCG(5th IS 2013.
4. *Biosite Assay for Triage BNP, Instructions for Use, Part No. 22402 Rev. J, Inverness Medical, 2009*

Note: Two new Access2 instruments were placed in service on July 23, 2015

Associated Documents:

External Documents

Appendix A: CK-MB Example CKMB Dilution example..docx [

ED Troponin TAT Process Improvement.pdf

Associated Documents:

SFOFCD-0199 -- QS - Chemistry Access 2 Calibration Worksheets
SFOFCD-0229 -- CHEM - Beckman TnI Repeat Testing Form

Click to Open an Associated Document

Documents Generated:

Document Revision History:

Revision: 24	**Date Created:** 09/01/2005 **Date of Last Revision:** 06/24/2019	**Last Approval Date:** 06/24/2019

Document Author: Kevin W LUI/CA/KAIPERM	

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Transfer from existing format.	11/16/07
2	Specimen section	Clarified sample integrity	07/08/08
3	Control - CKMB CRR Reporting results - CKMB iii	highest calibrator value as high CRR > twice the Highest calibrator -----	2/25/09
4	All sections for PTH IO	Adding PTH Io assay through out the procedure	10/28/09
5	Specimen - Note Reporting results -Sec 4.c	Added the note to double spin all positive Troponin results. Flow chart for resulting Troponin results.	11/2/10
6	Reporting results - Sec 4 c	Flow chart deleted and any result >/=0.09 ng/mL will be verified only after confirming	11/22/11

		with a double spin plasma	
7	Sec B.1.D	Section on Calibration verification procedure deleted and moved up Performing Quality control Linked Calibration worksheet - Approved FCD 198 document	3/14/2012
8	Specimen requirement table A. Maintenance 5-check the substrate bottle A. Maintenance 13 - II.Weekly maintenance Reporting results -4.c,d,e	Specimen type for Troponin changed to RST and Specimen stability for all except BNP changed to differentiate spun and Unspun Substrate warming minimum and maximum number of days Expiry date for System check solution Deleted <0.09 ng/ml, d and changed e to d	7/30/12
9	Specimen Reporting Results Approvers	Deleted plasma, plain red and SST tubes Revised entire section for Millennium Change of CLIA Director	3/22/2013
10-11	N/A	Computer glitch, versions skipped	2/1/14
12	Specimen requirement table Reporting results for Troponin (4.c.ii)	ß-hCG specimen spin as soon as possible First positive troponin to confirm with other Access-2	2/10/14
12	Throughout Specimen Requirement Table Sample Processing, Calibration B1Cl, B1Cm i-iv, Reporting Results , 4b.4ci, 4d1ii	Change all aTnI to aTnI+3 CK-MB, delete Plain Red and Red SST as sample types; TropI, Add Centrifuge within 2 hours of collection, spin sample on gel barrier only once, sample volume 205ul; BNP, change stability to 7 hours at room temp or refrigerated Add Access2 Calibration worksheet and record temperature for BNP cal; Add patient correlation. Upper reportable changed to 90 ng/ml. Add "aliquot the sample into a micro-centrfuge tube.." Delete sentence from templae, "Assay maximum upper reportable range (detection) value is 100.00 ng/ml"	2/25/14
13	Throughout document Specimen Requirements Table Priniciple e A10 Sec C Calibration Table Combine former Sec B2 and QC into one section F Table, G4, H4 Add new section I New Assoiciated Document	Reformat, renumber entire document Update per Instructions for use Delete " PTH for paratthyroidectomy patients" System Backup instructions added Update Storage & stability New section D for QC New TropI AMR, reference range, interpretation and criteria for handling repeat results. Interfering Substances Beckman TnI Repeat Testing Log,	7/18/2014 7/24/2014 7/30/2014
14	Throughout document Specimen Requirements Table C. Calibration F. AMR & CRR, G. Reference Range, H1a-d. Reporting Results E2, Sample Processing	Change reagent name from TßhCG to HCG5 and on board test name from TßhCG2 and Dil-TßhCG to HCG5 and HCG5d Update for HCG5 reagent, add Troponin-I sample volume New HCG5 calibrator, Reportable limits, Reference Range and Interpretative Comment. Add manual dilution instructions PTH IO results called to O.R.	10/31/2014

	I3 Interferece/Limitations	HCG5 dilutions	
15	A10. System Backup F. AMR & CRR H1b, c . Reporting Results	Add backup with flash drive. Change upper reportable limit to 375,000 mIU/mL. Change manual dilution to 2, upper limit to 375,000 mIU/mL	1/12/2015
16	A10 System Backup H3c CKMB Reporting I1, I2 References End of Document	Delete instructions for performing tape backup. Correct template from "CKMB" to "CKMBI Update Reference publications. Added note, re: New Access2 in use	7/22/2015
17	D.1.b. Quality Control	Correct stability of Bio-Rad Specialty Immunoassay control from 30 days to 23 days	12/9/2015
18	F, G, H	Edit for Linear Limits added in RILIS: BNP upper limit changed from 4900 to 4500. PTH IO upper limit changed from 30,000 to 3000 (delete instructions for dilution). CK-MB, add instructions for determining dilution factor. Upper limit changed from 300 to 270. Test / Low Limit / High Limit BNP / 1 / 4500 PTH IO / 6 / 3000 CK-MB / 0.1 / 270.0	4/12/2016
19	A2. Daily Maintenance A4. Daily Maintenance A4 B2 Weekly Maintenance D1b. Control table H Reporting Results H3b3 Reporting CK-MB >270 Approvers	Delete inspection of waste bottle Delete instructions for changing waste bottle. Waste drains directly to sink. Renumber remaining sections A4-A12 Delete inspection/cleaning of waste filter bottle and renumber sections B2-B5 Edit format, add details for PTH IO aliquots. Delete all images of LIS function icons/keys. Many changed with CM upgrade on June 18. CK-MB example added in Appendix A Delete J.Fang, add E. Suba	6/27/2016
20		Change in Associate Pathologist	12/12/17
21	Reporting Results	Repeat of first time positive Trop I results is discontinued.	09/14/18
22.	Added PDF for Troponin workflow.	Added PDF explaining steps for bench CLS to follow to improve Troponin TAT, Changed Director	2/15/2019
23	Quality Control	Updated QC Stability	6/13/19

Notification List:

Approvals:

First Approver's Signature

Name: Vaiju Ruikar/CA/KAIPERM — Jun 19, 2019 09:17:07 AM PDT - Approved by: Vaiju Ruikar/CA/KAIPERM
Title: Assistant Lab Administrative Directorr

Second Approver's Signature

Name: Elizabeth M Hosfield/CA/KAIPERM — Jun 24, 2019 08:16:46 AM PDT - Approved by: Elizabeth M Hosfield/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Document History Section