



## **ACCESS QUALITY CONTROL**

### **PRINCIPLE**

The use of Biorad and specific BNP assayed controls are used to monitor the performance of the Beckman Coulter Access II chemistry system.

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period. Include commercially available quality control materials that cover at least two levels of analyte. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Follow manufacturer's instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results

### **SCOPE**

All Medical Technologists and Medical Laboratory Technicians working at the Franklin Laboratory.

### **SPECIMEN REQUIREMENTS**

- BNP and Biorad control material.

### **EQUIPMENT AND MATERIALS**

1. Beckman Coulter Access II Analyzer(Franklin Facility ID# 982972/SN #504760)
2. Beckman Coulter Access reaction Vessels Ref#81901
3. Beckman Coulter Access Waste Bags Ref#81904
4. Transfer Pipettes Item # 9990 5580
5. Biorad Liquid controls

6. BNP liquid controls.

- **STORAGE AND STABILITY**

1. Quality control samples are stored frozen in the -70 °C freezer and stable per indicated expiration date on the bottle.
2. Once thawed and opened, quality control samples stored in 2 – 8°C and are stable up to 14 days.
  - a. Once thawed, the control should not be refrozen.
  - b. Before sampling, allow the control to reach room temperature and swirl gently to ensure homogeneity.

## **REAGENTS**

1. Triage BNP and Biorad QC Controls or other commercially available control material. Cat. No. 98201
2. Biorad Immunoassay Plus Control Levels 1, 2 and 3: (Biorad Level 1: #361, Level 3: #363)
3. Access Substrate. Cat. No. 81906
4. Access Wash Buffer II. Cat. No. A16792
5. Beckman Coulter Access 2 analyzer.
6. BNP, Progesterone, Estradiol, LH and BhCG Access II pack reagents.(See procedures for specifics.)

## **PROCEDURE**

1. Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays.
2. Since samples can be processed at any time in a “random access” format rather than a “batch” format, quality control materials should be included in each 24-hour time period .
3. Once per 24 hour period, run all three levels of the BioRad Hormone controls level 1, level 2, and level 3, and BNP controls.
4. Acceptable quality control ranges:
  - a. See posted control acceptable ranges on the instrument
  - b. Setup in CERNER – QC BD maintenance application. Ranges will apply when QC results are entered into the LIS

5. Loading controls on the instrument – Step by step instructions

- a. Access sample manager on the touch screen
- b. Enter Rack ID-Wand the pink rack bar code (Used for 0.5 ml cups)-Press enter
- c. Select test request
- d. Select request QC (F5)
- e. Select sing or multi-level quality controls. (br1, br 2 and br 3, and BNP 1, BNP 2, and BNP 3)
- f. Select OK
- g. Select Load (Look at the screen to verify if you can load the cassette on the instrument)
- h. Load the cassette/Rack on the instrument
- i. Select Done
- j. Select Run

**REPORTING RESULTS**

Quality Control results are entered in the “ARE” application of CERNER.

-At the accession # prompt type for hormones:

**0-QC-020731 for Level 1**

**0-QC-020732 for Level 2**

**0-QC-020733 for Level 3**

-At the accession # prompt type for BNP’S:

**0-QC-027701 for Level 1**

**0-QC-027702 for Level 2**

**0-QC-027703 for Level 3**

-Click on PERFORM

-Click on VERIFY

Quality control samples are stored frozen in the  $-70^{\circ}\text{C}$  freezer and stable per indicated expiration date on the bottle.

Once thawed and opened, quality control samples stored in  $2 - 8^{\circ}\text{C}$  and are stable up to 14 days.

## **REFERENCE RANGES**

-Refer to charts and graphs on instrument as well as Cerner ranges in LIS.

## **LIMITATIONS OF THE PROCEDURE**

-Refer to troubleshooting section in "Quick Reference Guide" for specific QC and instrument errors.

-Call Service for any issue that can not be addressed.