KAISER PERMANENTE®
COLORADO LABORATORY

ACCESS II CALIBRATION

PRINCIPLE

An active calibration curve is required for all tests run on the Access II. At the Franklin laboratory this includes Beta HCG's, Progesterones, Estradiol, hLH, and BNP testing. Calibration is required every 28 days or as needed.

Quantitative assay calibration is the process by which samples with known analyte concentrations (i.e., assay calibrators) are tested like patient samples to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. This mathematical relationship, or calibration curve, is used to convert RLU (Relative Light Unit) measurements of patient samples to specific quantitative analyte concentrations.

SCOPE

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

SPECIMEN REQUIREMENTS

No patient samples required, only specific reagent calibrators.

REAGENTS

1. Access Substrate. Cat. No. 81906
2. Access Wash Buffer II. Cat. No. A16792
3. Beckman Coulter Access 2 analyzer.
4. Access **Total BhCG** Calibrators-Cat No 33505 S0-S5, 4.0 ml/vial
    - Provided ready to use.
    - Store at -20°C.
    - Thaw at room temperature and mix contents by gently inverting before use. Avoid bubble formation.
    - Return calibrators to -20°C after each use.
    - Stable until the expiration date stated on the label when stored at -20°C.

- Signs of possible deterioration are control values out of range.
- Refer to calibration card and or vial labels for exact concentrations.

5. Access **Estradiol** Calibrators-Cat No 33545 S0, 4.0 ml/vial; S1-S5 2.5 ml/vial
    - Provided ready to use.
    - Store upright and refrigerate at 2 to 10°C.
    - Mix contents by gently inverting before use. Avoid bubble formation.
    - Stable until the expiration date stated on the label when stored at 2 to10°C.
    - Signs of possible deterioration are control values out of range.
    - Refer to calibration card for exact concentrations.
6. Access **Progesterone** Calibrators-Cat No. 33555; S0, 4ml/vial; S1 – S5 2.5 ml/vial
    - Provided ready to use.
    - Store at -20°C.
    - Mix contents by gently inverting before use. Avoid bubble formation.
    - Stable until the expiration date stated on the label when stored at -20°C.
    - After thawing, calibrators are stable for 3 months at 2 to 10°C.
    - Signs of possible deterioration are control values out of range.
    - Refer to calibration card for exact concentrations.
7. Access **hLH** Calibrators-Cat No 33515: S0-S5, 4.0 ml/vial
    - Provided ready to use.
    - Store upright and refrigerate at 2 to 10°C.
    - Mix contents by gently inverting before use. Avoid bubble formation.
    - Stable until the expiration date stated on the label when stored at 2 to10°C.
    - Signs of possible deterioration are control values out of range.
    - Refer to calibration card for exact concentrations.

8. Triage **BNP** Calibrators-Cat No 98202: S0-S5, 1.5 ml/vial
    - Provided ready to use.
    - Stable until the expiration date stated on the label when stored at -20 °C or colder.
    - Vial is stable at 2 to 10 °C for 30 days after initial use.
    - Signs of possible deterioration are control values out of range.

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

PROCEDURE-Calibration

1. Loading calibrators on the instrument – Step by step instructions.
    a. Access sample manager (F1) on the touch screen
    b. Select off-board rack or enter rack ID – press enter.
    c. Test Request (F3) – Request Calibration (F6)
    d. Select Calibration setup for Test(BhCG,Est,LH,Prog, or BNP)(F1-OK)
    e. System enters calibration set lot number, calibrator levels, and reagent pack lot number.
    f. Test Request for appropriate test and reagent pack lot # – system enters each calibrator level in subsequent sample positions.
    g. Select load rack (F1)
    h. Add Samples to rack and load rack.
    i. Select Run
2. An active calibration curve is required for all Tests
3. BHCG
    - For the Access TotalβhCG assay, calibration is required every 28 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

- The Access TotalβhCG Calibrators are provided at six levels - zero and approximately 5, 25, 150, 500 and 1000 mIU/mL - prepared gravimetrically from purified hCG and buffered BSA matrix. Assay calibration data are valid up to 28 days.
- **Calibrators run in duplicate.**

4. Estradiol

- For the Access Estradiol assay, calibration is required every 14 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.
- The Access Estradiol Calibrators are provided at six levels - zero and approximately 106, 570, 1800, 3100, and 4800 pg/mL – prepared from synthetic estradiol and human serum. Assay calibration data are valid up to 14 days.
- **Run the Access Estradiol S0 and S1 Calibrators in quadruplicate,** and the S2–S5 Calibrators in duplicate.

5. Progesterone

- For the Access Progesterone assay, calibration is required every 28 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.
- The Access Progesterone Calibrators are provided at six levels - zero and approximately 1.0, 4.0, 10.0, 20.0 and 40.0 ng/mL - prepared gravimetrically from synthetic progesterone and human serum. Assay calibration data are valid up to 28 days.
- **Run the Access Progesterone Calibrator S0 in quadruplicate, the S1 calibrator in triplicate**, and the S2-S5 calibrators in duplicate

6. LH

- For the Access hLH assay, calibration is required every 28 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.
- The Access hLH Calibrators are provided at six levels - zero and approximately 2, 10, 25, 100 and 250 mIU/mL prepared gravimetrically from purified hLH and buffered BSA matrix. Assay calibration data are valid up to 28 days.
- **Calibrators run in duplicate**

7. BNP

- For the Triage BNP test, calibration is required every 28 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.
- The Triage® BNP Calibrators are provided at 6 levels - zero and approximately 25, 100, 500, 2500 and 5000 pg/mL. Assay calibration data are valid up to 28 days.
- **Calibrators run in duplicate.**

REPORTING RESULTS

- No results should be reported until completion of calibration and appropriate QC that are within limits.

REFERENCE RANGES

- Calibration results to fall within acceptable limits.

LIMITATIONS OF THE PROCEDURE

- If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

REFERENCES

- See individual test procedures for specific references.