# CHEM.COBAS.ASSAY.20.0 STAT PTH by Cobas e411

## STATEMENT OF PURPOSE

The STAT PTH method on the Cobas e411 is measured by an electrochemiluminescence immunoassay (ECLIA) for in vitro quantitative determination of intact parathyroid hormone in human serum and plasma. Intact PTH in the sample is incubated with a biotinylated monoclonal PTH-specific antibody and a monoclonal PTH-specific antibody labeled with a ruthenium complex to form a sandwich complex. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Results are determined by a calibration curve which is generated by a 2-point calibration and a master curve provided via the reagent barcode.

## SCOPE

Applies to all STAT PTH testing performed on Cobas e411.

## OWNERS

Technical Supervisor, St. Vincent Evansville

## RELATED DOCUMENTS

CHEM.COBAS.2.0 Cobas e411 Operating Procedure
CHEM.COBAS.2.1 Cobas e411 Maintenance Procedure
CHEM.COBAS.2.2 Cobas e411 Maintenance Log

## SPECIMEN

A. Specimen type: EDTA plasma is the only acceptable specimen in the intraoperative setting due to the need for rapid testing and reporting of results.
B. Preparation of samples
    1. Centrifuge samples according to manufacturer's instructions to separate the plasma from the cells.
    2. Before placing samples on the e411, ensure they are free of fibrin, particulate matter and bubbles.

C. Specimen rejection criteria
   1. Any anticoagulant other than EDTA
   2. Hemolyzed samples
   3. Unlabeled or mislabeled tubes
D. Sample stability
   1. Plasma is stable for 2 days at 15-25°C, 3 days at 2-8°C or 6 months at -20°C.
   2. Prior to analysis, refrigerated or frozen samples should be brought to 20-25°C and mixed thoroughly.
E. The sample required for analysis is 50uL + 150uL of dead space for a total of 200uL.

**MATERIALS**

A. PTH STAT CalSet
B. ProCell
C. CleanCell
D. Elecsys SysWash
E. Elecsys AssayCup
F. Elecsys AssayTip
G. Elecsys SysCLean
H. Controls

**REAGENTS**

A. The reagent rackpack is labeled as PTH-STAT. The pack consists of:

- M – Streptavidin-coated microparticles (transparent cap)
- R1 – Anti-PTH-Ab~biotin (gray cap)
- R2 – Anti-PTH-Ab~Ru(bpy) (black cap)

B. Reagent handling
   1. The reagents in the kit have been assembled into a ready-to-use unit that cannot be separated.
   2. Avoid foam formation in all reagents.
   3. All reagents should be allowed to equilibrate to room temperature approximately 45 minutes prior to placing on the analyzer.
C. Storage and stability
   1. Store at 2-8°C.
   2. Store in an upright position in order to ensure complete availability of the microparticles during automatic mixing prior to use. **DO NOT MIX** prior to placing on the analyzer.
   3. Reagent is stable
      a. Until the expiration date stated on the reagent when stored unopened at 2-8°C

b. 12 weeks after opening when stored at 2-8°C
c. 8 weeks on the analyzer

**EQUIPMENT**

Cobas e411

**CALIBRATION**

A. Frequency
   1. Lot calibration must be performed on a new or expired lot within 24 hours of placing the pack on the analyzer. Lot calibration is stable for 12 weeks.
   2. Reagent pack calibration is performed approximately every 7 days on packs that have been on-board the analyzer for more than 24 hours.

B. PTH CalSet
   1. Preparation and storage
      a. Reconstitute with 1.0mL of DI water and allow to stand closed for 15 minutes. Mix carefully avoiding foam formation.
      b. Transfer the reconstituted calibrators into the supplied empty labeled snap-cap bottles.
      c. The reconstituted calibrators should only be left on the instrument during calibration. After use, close the bottles as soon as possible and store upright at 2-8°C.
      d. Stability
         1. Lyophilized calibrators are stable until the stated expiration date.
         2. Reconstituted calibrators are stable for 5 uses on the e411, 2 weeks at 2-8°C or 3 months at -20°C.

C. Refer to CHEM.COBAS.2.0 for calibration instructions.

D. Calibration acceptability – review the calibration results. The calibration is acceptable if the slope is within 0.900-1.100.

**QUALITY CONTROL**

A. A minimum of two levels of controls spanning the medical decision range are to be run once every 24 hours of assay use. See QC procedure LAB.GEN.QC.2.0 for specific details.
B. See QC package insert for preparation, storage and stability instructions.
C. See CHEM.COBAS.2.0 for instructions.

**PROCEDURE**

See CHEM.COBAS.2.0 for operating procedures.

**REPORTING RESULTS**

A. Using function REH, the laboratory will order test IPTH or PTPTH with STAT priority for each patient. If there are more than 6 specimens for IPTH, the test code PTHX must be REH'd for each additional specimen.
B. Results are reported in Sunquest using function MEM.
C. To report IPTH, follow the following steps:
    1. Worksheet: Site specific
    2. Method: Site specific
    3. PTHNO: Enter the total number of PTH specimens
    4. PTH1D: Enter the description of the first specimen
    5. PTH1T: Enter the collection time of the first specimen
    6. PTH1R: Enter the result of the first specimen
    7. PTH2D: Enter the description of the second specimen
    8. PTH2T: Enter the collection time of the second specimen
    9. PTH2R: Enter the results of the second specimen
    10. Repeat for all specimens received.
D. Specimen descriptions
    1. Baseline: enter English text code BSL
    2. Pre-excision: enter English text code PRX
    3. Any other description: free text the description, preceding it with ";", i.e. ;10 minute post excision
    4. No description given: enter English text code NOTG
E. Specimen collection time: enter using the 24-hour clock, i.e. 0910
F. Specimen results: enter result in whole numbers.
G. All members of the IPTH battery not needed will automatically be answered with HIDE.
H. If there are 6 specimens, after the first 5 have been answered, it will be necessary to accept those (at the A-M-R prompt) and then re-enter the same accession number to answer the 6th one.

**PROCEDURE NOTES**

A. AMR: 1-5000 pg/mL
B. Results greater than 5000 will be reported as >5000. No dilutions are necessary.
C. Results less than 1 will be reported as <1 pg/mL.
D. Expected values: 15-65 pg/mL

**LIMITATIONS**

A. Do not analyze samples that show visible signs of hemolysis. The assay is affected by hemolysis ≥ 0.25g/dL.
B. The assay is unaffected by icterus (bilirubin < 65 mg/dL), lipemia (<1500 mg/dL) and biotin (<50 ng/mL).
C. Samples should not be taken from patients receiving therapy with high biotin doses (i.e.>5 mg/day) until at least 8 hours following the last biotin administration.
D. There is no high-dose hook effect at PTH concentrations of up to 17000 pg/mL.

**REFERENCES**

A. PTH STAT package insert, 2016-03, V 6.0
B. PTH STAT CalSet package insert, 2015-11, V 6.0