**CHEM.DXI.ASSAY.3.0 DXI INTACT PTH (PTH)**

**PRINCIPLE** The Access Intact PTH assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of intact parathyroid hormone (parathyrin, PTH) levels in human serum and plasma using the Access Immunoassay System. It is indicated to aid in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy and can be used intraoperatively. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decision The Access Intact PTH assay is a two-site immunoenzymatic (“sandwich”) assay. A sample is added to a reaction vessel, along with a monoclonal anti-PTH- antibody conjugate to alkaline phosphatase, TRIS buffered saline with proteins and paramagnetic particles coated with a goat polyclonal anti-PTH antibody. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos\* 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of PTH in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

**OWNERS** Manager, Regional Chemistry

**RELATED DOCUMENTS**

CHEM.DXI.1.0 DXI Operating Procedure

**SPECIMEN**

A. Specimen Type

 1. Serum

 2. Plasma (heparin, EDTA)

B. Specimen Stability

 1. Room Temperature (15-30°C) – 8 hours (SERUM 4 HOURS))

 2. Refrigerated (2-8°C) – 48 hours (SERUM 8 HOURS)

 3. Frozen (<-20°C) – 6 months or for shipment

C. Special Instructions

 1. Thaw specimens no more than three times.

 2. Avoid assaying lipemic or hemolyzed samples.

**REAGENTS**

A. The reagent is ready to use.

B. Store upright and refrigerate at 2-10°C.

C. Refrigerate at 2-10°C for a minimum of two hours before use on the instrument.

D. Stable until the expiration date on the label when stored at 2-10°C.

E. Stable at 2-10°C for 28 days after initial use.

F. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading onto the instrument.

G. Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.

H. If the reagent pack is damaged (i.e., broken elastomer), discard the pack.

I. All antisera are polyclonal unless otherwise indicated.

J. For in vitro diagnostic use.

K. Handle all reagents with caution and avoid contact with skin, eyes, or mouth. Refer to the Method Manual for any known toxicity.

**EQUIPMENT**

Beckman Coulter Access UniCel DxI 600

**CALIBRATION**

A. An active calibration curve is required for all tests.

B. Calibration is required every 28 days for Access PTH.

C. Calibrators are Ready to Use.

D. Store upright at 2-10°C.

E. Mix contents by gently inverting before use

F. Stable until the expiration date stated on the label when stored at 2-10°C.

F. Refer to calibration card for exact concentrations.

G. Refer to the appropriate system manual and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

**QUALITY CONTROL**

1. Refer to CHEM.QC.REGIONAL.2.0 Quality Control Testing Intervals for QC Testing Intervals for appropriate control materials and testing intervals.
2. Refer to CHEM.QC.REGIONAL.1.0 Regional Chemistry laboratory Quality Control for criteria on accepting/rejecting patients based on control results.
3. Refer to CHEM.QC.REGCHEM.2.2 QC PREP and STABILITY

**PROCEDURE**

A. See, DxI Operating Procedure, CHEM.DXI.1.0 for specific details.

B. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

**DILUTIONS** A. for auto or manual dilution refer to CHEM.DXI.1.2 for specific details.

The DxI system onboard dilution feature automates the dilution process, using predefined assay sample and the Wash Buffer/ Sample Diluent volumes, allowing samples to be quantitated. Results Reported by the system are adjusted for dilution.

**REPORTING RESULTS**

Refer to, CHEM.DXI.1.1 for Test Codes, AMR, CRR, Critical and Normal Ranges

**RESULT ENTRY**

A. Sunquest

 1. OEM or MEM

 2. Worksheet: DXI

 3. Method: DXI

 4. Test Code: PTH

B. Toplab

 1. Enter results in Toplab using Toplab Common Pathway: 3,3,1

 2. Toplab Worklist: DXI1

 3. Test Code: 8837

C. If HIS or LIS systems are not functional, see the Computer Downtime CHEM.LIS.5.0 procedure.

**PROCEDURE NOTES** Use 250 µL of sample for each determination run with the DXI system.

**LIMITATIONS**

A. For assays employing antibodies, the possibility exists for 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, that interferes with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.

B.The Access PTH results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests and other appropriate information. It is well documented that PTH concentrations are influenced by several factors known to synergistically affect calcium homeostasis. Age, gender, geographic latitude, season of the year, skin pigmentation, sunlight exposure, vitamin D supplementation , kidney function and vitamin D insufficiency have all been reported to potentially affect PTH metabolism and impact reference values and decision thresholds.

**REFERENCES** A. Beckman Coulter Access Immunoassay Systems INTACT PTH Assay reagent insert (A57353D) 2011