CHEM.DXI.ASSAY.7.0 DXI TPO Antibody (TPO)

PRINCIPLE

The Access TPO Antibody assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroperoxidase antibody (TPOAb) levels in human serum and plasma using the Access Immunoassay Systems.

The Access TPO Antibody assay is a sequential two-step immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with paramagnetic particles coated with thyroperoxidase protein. The serum or plasma TPOAb binds to the thyroperoxidase. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. The Protein A-alkaline phosphatase conjugate is added and binds to the TPOAb. After the second incubation, 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 TPOAb in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve

OWNERS

Manger, Regional Chemistry

RELATED DOCUMENTS

CHEM.DXI.1.0 DXI Operating Procedure
CHEM.ARCH.ASSAY 87.1 Thyroid Cascade Flowchart

SPECIMEN

A. Specimen Type
1. Serum
2. Plasma (lithium heparin or EDTA)

B. Specimen Stability
1. Room Temperature (15-30°C) – 8 hours
2. Refrigerated (2-8°C) – 48 hours
3. Frozen (≤-20°C) ->48 hours or for shipment

C. Special Instructions
1. Thaw samples no more than three times
2. Avoid assaying lipemic or hemolyzed specimens

REAGENTS

A. Reagent is provided 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. Mix contents of new (un-punctured) reagent packs by gently inverting pack several times before loading on the instrument.

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

F. Stable at 2-10°C for 56 days after initial use.

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

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

I. Access Substrate

1. Provided Ready to Use
2. Stability

Condition	Storage	Stability
Unopened	2-8°C	Until expiration date on label
Equilibration prior	15-30°C	Minimum 18 hours
To use (Unopened)		Maximum 14 days
In Use (Opened)	External Fluids tray Substrate Position	Maximum 14 days

J. Access Wash Buffer

1. Provided Ready to Use
2. Stable until the expiration date on the label when stored at room temperature (15-30°C).
3. An increase in substrate background measurements or increased relative light units for the Zero calibrators in “sandwich”-type assays may indicate instability.

EQUIPMENT

Beckman Coulter Access UniCel DxI 600

CALIBRATION

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

1. Calibrators are Ready to Use
2. Store upright and refrigerate at 2-10°C
3. Mix contents by gently inverting before use
4. Avoid bubble formation
5. Stable until expiration date on label when stored at 2-10°C.
6. Vial is stable at 2-10°C for 120 days after initial use.
6. Refer to calibration card for exact concentrations.

B. Calibration is required every 56 days.

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

A. **QUALITY CONTROL**
Refer to CHEM.QC.REGIONAL.2.0 Quality Control Testing Intervals for QC Testing Intervals for appropriate control materials and testing intervals.
B. Refer to CHEM.QC.REGIONAL.1.0 Regional Chemistry laboratory Quality Control for criteria on accepting/rejecting patients based on control results.
C. 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: TPABY

B. Toplab
1. Enter results in Toplab using Toplab Common Pathway 3,3,1
2. Worklist: DXI1
3. Test Code: 5081

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.
B. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have received immunotherapy or diagnostics procedures utilizing

immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interferes with immunoassays. Such interfering antibodies may cause erroneous results.

C. The test result in and of itself is not diagnostic for thyroid disease and should be considered in conjunction with iodine uptake and other standard thyroid tests and the clinical presentation of the patient.

D. Moderately increased levels of TPO antibody may be found in patients with non-thyroid autoimmune disease such as pernicious anemia, type I diabetes mellitus, or other disorders which activate the immune system.

LIMITATIONS

Interfering Substances: Refer to the Method Manual for drugs and other substances tested for interference.

REFERENCES

A. Beckman Coulter TPO Antibody Assay Procedure (A83813B). 2010.