CHEM.DXI.ASSAY.6.0 DXI Thyroglobulin Antibody (Tg-Ab)

PRINCIPLE

The Access Thyroglobulin II assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Thyroglobulin Antibody in human serum or plasma using the Access Immunoassay Systems.

The Access Thyroglobulin II assay is a sequential two-step immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with paramagnetic particles coated with the thyroglobulin protein. The serum or plasma ATG binds to the thyroglobulin. 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 thyroglobulin-alkaline phosphatase conjugate is added and binds to the ATG. After a 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 thyroglobulin antibody in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

OWNER

Manger, Regional Chemistry

RELATED DOCUMENTS

CHEM.DXI.1.0 DXI Operating Procedure

SPECIMEN

A. Specimen Type
    1. Serum
    2. Plasmas (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 two times

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 (unpunctured) 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. Calibrators

1. Provided 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. 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.

QUALITY CONTROL

A. 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: THYAB
B. Toplab
    1. Enter results in Toplab using Toplab Common Pathway 3,3,1
    2. Worklist: DXI1
    3. Test Code: 267
C. If HIS or LIS systems are not functional, see the Computer Downtime CHEM.LIS.5.0 procedure.

PROCEDURE NOTES

A. 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.

LIMITATIONS

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

REFERENCES

A. Beckman Coulter Thyroglobulin Antibody II Assay Procedure (A38188E). 2011