CHEM.DXI.ASSAY.5.0 DXI Thyroglobulin (Tg)

PRINCIPLE

The Access Thyroglobulin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin levels in human serum and plasma using the Access Immunoassay Systems. This device is intended to aid in monitoring for the presence of local and metastatic thyroid tissue in patients who have had thyroid gland ablation (using thyroid surgery with or without radioactivity) and who lack serum thyroglobulin antibodies.

The Access Thyroglobulin assay is a simultaneous one-step immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel, along with biotinylated mixture of four monoclonal ant-Tg antibodies, streptavidin coated paramagnetic particles, and monoclonal anti-Tg antibody alkaline phosphatase conjugate. The biotinylated antibodies and the serum or plasma thyroglobulin binds to the solid phase, while the conjugate antibody reacts with a different antigenic site on the thyroglobulin molecule. 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 thyroglobulin 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. Plasma (heparin)

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 only once

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 28 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.

K. Thyroglobulin Sample Diluent

1. Provide Ready to Use
2. Allow the contents to stand for 10 minutes at room temperature.
3. Mix gently by inverting before use.
4. Stable until the expiration date on the vial label when stored at 2-10°C.

EQUIPMENT

Beckman Coulter Access UniCel DxI 600

CALIBRATION

A. Calibrators

1. Provided Lyophilized
2. Reconstitute each vial volumetrically with 2mL CWRL. Allow 30 minutes for dissolution.

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. Reconstituted stability is 4 months 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

Thyroglobulin (THYRR) is a component of THYR panel (THYRR, THYAB) and is not orderable as an individual test.

A. Sunquest

1. OEM or MEM
2. Worksheet: DXI
3. Method: DXI
4. Test Code: THYRR

B. Toplab

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

2. Worklist: DXI1
3. Test Code: 30278

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 been regularly exposed to animals or have received immunotherapy or diagnostics procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere 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.

C. Samples containing thyroglobulin antibodies (TgAb) cannot be reliably measured. All samples should be screened for Tg antibodies, and samples which are TgAb antibody positive should be interpreted with caution as the true value may be higher than that obtained.

LIMITATIONS

A. Interfering Substances:

B. Refer to the Method Manual for drugs and other substances tested for interference.

REFERENCES

A. Beckman Coulter Thyroglobulin Assay Procedure (A34085D). 2010