



To: Medical Staff, Nursing Units, and Laboratory Clients

From: Stephen C. Ingels, M.D. and Eric Thompson, M.D.

Subject: Beckman Coulter Access TPO Antibody assay

Date: September 1, 2023

Norman Regional Laboratory services is now offering the Beckman Coulter Access TPO Antibody assay.

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 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.

#### **ANALYTICAL SENSITIVITY**

The lowest detectable level of thyroperoxidase antibodies distinguishable from zero (Access TPO Antibody Calibrator S0) with 95% confidence is 0.25 IU/mL. This value is determined by processing a complete six point calibration curve, controls, and 10 replicates of the zero calibrator in multiple assays. The analytical sensitivity value is interpolated from the curve at the point that is two standard deviations from the mean measured zero calibrator signal.

#### **CLINICAL SENSITIVITY**

The Access TPO Antibody assay was further evaluated using sera obtained from 54 patients diagnosed with Hashimoto's Thyroiditis and 40 patients diagnosed with Graves' Disease. The diagnosis of Hashimoto's Thyroiditis and Graves' Disease was based upon criteria established by the individual laboratory. The presence of TPO antibodies was not a criteria for disease diagnosis.

## **Test Results**

The determination of TPOAb levels is the most sensitive test for detecting autoimmune thyroid disease<sup>3</sup>. The highest TPOAb levels are observed in patients suffering from Hashimoto's thyroiditis. In this disease, the prevalence of TPOAb is about 90% of cases confirming the autoimmune origin of the disease. These autoantibodies also frequently occur (60-80%) in the course of Graves' disease.

There is a good association between the presence of autoantibodies against TPO and histological thyroiditis. However, in view of the extensive regenerative capacity of the thyroid under the influence of TSH, chronic thyroid disease may be present for years before the clinical manifestation of hypothyroidism becomes evident, if ever.

### Test Info:

- Go Live Date: September 1, 2023
- Test Name: TPOAB
- Acceptable specimen type: Serum (gel and no gel)
- Specimen Stability: 2 days 2 to 8°C.
- Expected Turnaround time: 8 hours (Routine)

For questions about this change, please call Kenneth Dohm (Clinical Lab Manager) at (405) 307-1114, or a pathologist at (405) 307-1141.