Legacy Laboratory Services

Thyroglobulin and Thyroperoxidase Antibodies
New formulation will decrease values

December 2011

As of January 16, 2012, Legacy Laboratory Services will shift to a new formulation of reagent for Thyroglobin Antibodies (ATGQ) and Thyroid Peroxidase Antibodies (TPO). The reagent manufacturer, Siemens, has optimized these two assays to ensure alignment with the World Health Organization (WHO) and is requiring all their laboratory clients to change.

ATGQ and TPO assays are reformulated by the manufacturer.

Our laboratory has evaluated and verified the new assays for serum. **The limit of detection will be decreased for both assays. In addition, values will decrease compared to current lots, especially below 100 U/mL.** Data from in-house studies comparing patients on new and current lots can be found in Figure 1. Optimization will correct the percentage of ATGQ and TPO values above the cut-off of 60 U/mL. The positive rate will decrease an estimated 7% (ATGQ) and 2% (TPO), respectively. The previous greater percentage of high values may lead to an overestimation of the future risk of thyroid disease for patients and hence additional follow up investigation. Reference Ranges (<60 U/mL) and specimen requirements will not change. The vendor does not expect any adverse effects on patient care. However, in order to ensure quality patient care, we will closely monitor the change and review reference ranges after two months using the new reagent.

If you have any further questions, please feel to contact us.

For additional information, contact:

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LEGACY HEALTH

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Figure 1: Comparing New to Current Assays -Serum from 53 patients was measured on both lots of the ATGQ and TPO assays. Results are from studies performed at Legacy Laboratory Services.

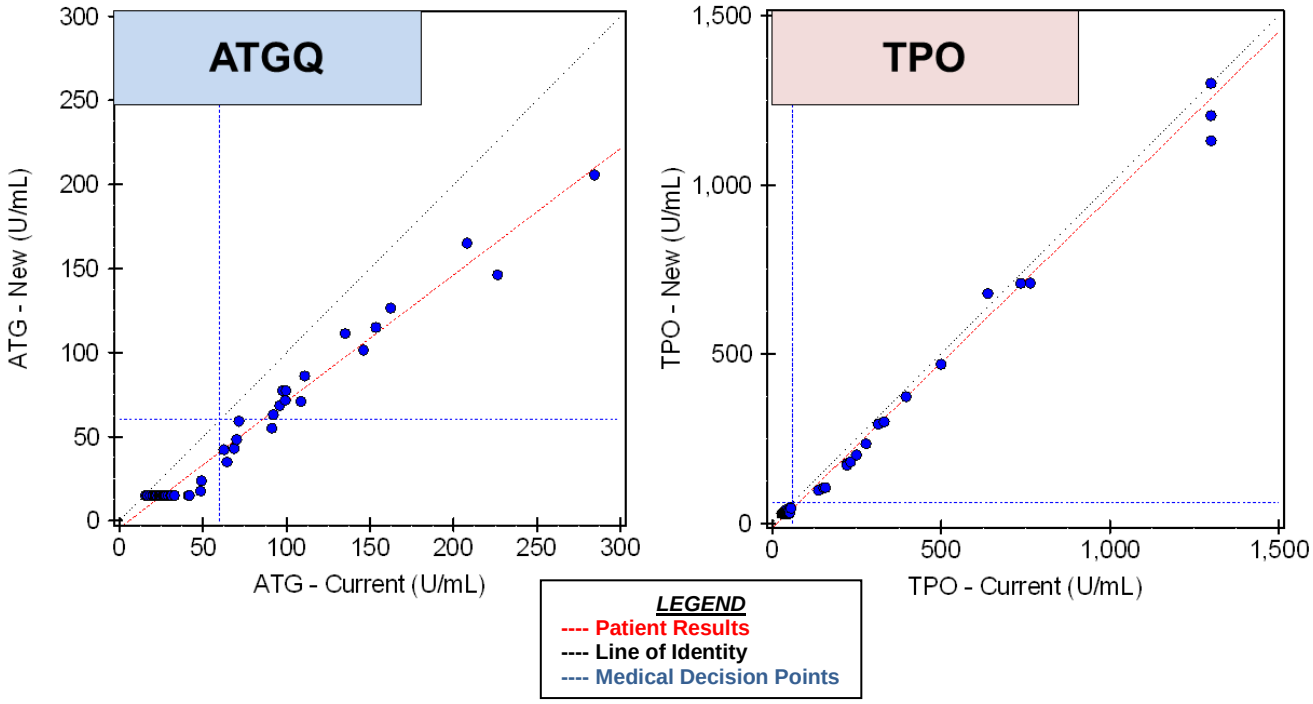

Table I: Collection Guidelines

Description	Thyroglobulin Antibody
Order Code	ATGQ

Description	Thyroid Peroxidase Antibody
Order Code	TPO

Collection Guidelines are the same for both.

Collect	Serum, one 5.0 mL gold (SST) or 7.0 mL red top tube
Handling	Allow serum to clot completely at room temperature (minimum: 30 minutes). Centrifuge and separate serum from cells ASAP.
Preferred Volume	1.0 mL serum
Minimum Volume	0.3 mL serum (whole blood 0.8 mL minimum draw)
Transport	Refrigerated (2-8°C)
Rejection Criteria	The following specimens will not be accepted: • Grossly hemolyzed specimens • Plasma
Stability (after separation from cells)	Temperature — Time Period Ambient (20-25°C) — 8 hours Refrigerated (2-8°C) — 48 hours Frozen (≤ –20 °C) — 2 months
Reference Ranges	< 60 U/mL