

May 3, 2009

**Reference Range Comment Change Notice: Comprehensive Thyroglobulin reflex to Thyroglobulin ICMA**

**Test Titles:** Thyroglobulin ICMA

**Esoterix Test Code:** 500316

**CPT Code:** 86800

**Effective Date:** June 8, 2009

**Explanation of change:** The reference range comment for the Thyroglobulin ICMA (part of the Comprehensive Thyroglobulin screen) will be changing. The new assay detection limit will be <0.1, which will be replacing the previous assay quantitation limit of <0.5. The change in the detection limit is due to a change in the platform from the current ICMA to a more sensitive ICMA platform. We have validated and correlated that the remainder of the reference range will remain the same.

Serum Thyroglobulin with the Comprehensive Thyroglobulin screen is an important test to monitor for thyroid cancer. Improved sensitivity also enhances the efficacy of the test for monitoring thyroid cancer after the thyroid has been removed.

Please refer to the attached chart for the changes in reference range. For additional information, please contact Client Services at 800-444-9111. We value you as a customer and thank you for choosing Esoterix.

Description	Predicate Method	New Method
Assay Method	Thyroglobulin ICMA (part of the Comprehensive Thyroglobulin Screen)	Thyroglobulin ICMA (part of the Comprehensive Thyroglobulin Screen)
Reference Range TG ICMA (ng/mL)	Pubertal Children and Adults: 1.3 – 37.0 Assay quantitation limit: <0.5	Pubertal Children and Adults: 1.3 – 37.0 Assay detection limit: <0.1
Sensitivity	LLOQ = 0.5 ng/mL	LLOD = 0.1 ng/mL
Assay Set frequency	Tuesday through Saturday	Tuesday through Saturday
Preferred Sample Requirement	5.0 mL serum (red top or SST/Tiger top), Frozen	5.0 mL serum (red top or SST/Tiger top), Frozen
Pediatric Minimum Sample Requirement	1.0 mL (note: minimum volume does not permit repeat analysis)	1.0 mL (note: minimum volume does not permit repeat analysis)