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Date: February 8, 2012

To: Clients of Hagerstown Medical Laboratory (HML)

From: John G. Newby, MD   
Director of Laboratories

Subject: New Thyroid Cancer Monitoring Test Panel is Replacing Existing Thyroglobulin, Serum Assay

Measurement of thyroglobulin (Tg) is useful in the detection of residual or recurrent thyroid cancer. Many individuals develop autoantibodies to Tg (Tg Ab) and recent studies indicate the presence of Tg Ab interferes with the measurement of immunoassay Tg. It is therefore necessary to identify the presence/absence of Tg Ab before measuring Tg.

The new Thyroid Cancer Monitoring Test Panel will first measure Tg Ab (Roche E170) an electrochemiluminescent assay and a highly sensitive test for the detection of endogenous anti-Tg antibodies.

- If the Tg Ab is negative ( $\leq 20$  IU/mL), Tg will be measured using an immunoassay (Second Generation, Beckman Coulter) - also a highly sensitive assay with increased low-level sensitivity to 0.05 ng/mL.
- If the Tg Ab is positive ( $> 20$  IU/mL), Tg will be measured by tandem mass spectrometry. The LC/MS/MS assay will provide quantitative measurement of Tg in the presence of Tg Ab.

On February 8, 2012, HML replaced the Thyroglobulin, Serum test (THYG) with the new Thyroid Cancer Monitoring Test Panel. Therefore, orders received for Thyroglobulin, Serum (THYG) after the conversion and going forward will automatically be converted to the new Thyroid Cancer Monitoring Test Panel. For your reference, a copy of the new test information sheet is attached. As before, this testing will be performed at Nichols Institute/Quest Diagnostics.

If you have questions or need additional information, please contact me by calling 301-665-4900 or 1-800-428-2105.

## Thyroid Cancer Monitoring

If Thyroglobulin Ab, ECL result is  $\leq 20$  IU/mL, then Thyroglobulin, Second Generation (Beckman Coulter) will be performed at an additional charge (CPT: 84432)

If Thyroglobulin Ab, ECL result is  $> 20$  IU/mL, then Thyroglobulin, LC/MS/MS will be performed at an additional charge (CPT: 84432).

### Test Code THYG

### Components Test includes:

- Thyroglobulin Antibody, Electrochemiluminescence
- Thyroglobulin, Second Generation (Beckman Coulter)
- Thyroglobulin, LC/MS/MS

### CPT Codes 86800

### Preferred Specimen 2.5 mL serum

### Instructions No sample should be drawn until at least 8 hours after last biotin administration.

### Transport Temperature Room temperature

### Specimen Stability Room temperature: 6 days Refrigerated: 7 days Frozen: 28 days

### Reject Criteria Plasma; hemolyzed, icteric, or lipemic specimens

### Methodology See individual assays

### Reference Range Thyroglobulin Ab, ECL: $<10$ IU/mL Thyroglobulin, Second Gen $<0.05$ ng/mL Thyroglobulin, LC/MS/MS: Adults: $<0.4$ ng/mL Reference range applies to differentiated thyroid cancer patients following treatment.

### Clinical Use Measurement of thyroglobulin (Tg) is useful in the detection of residual or recurrent thyroid cancer. Many individuals develop auto-antibodies to Tg (Tg Ab) and the presence of Tg Ab interferes with the measurement of immunoassay Tg. It is therefore necessary to identify the presence/absence of Tg Ab before measuring Tg. The panel will first measure Tg Ab (Roche E170) an electrochemiluminescent assay and a highly sensitive test for the detection of endogenous anti-Tg antibodies. If the patient is Tg Ab negative, Tg will be measured using an immunoassay (Second Generation, Beckman Coulter) - also a highly sensitive assay with increased low-level sensitivity to 0.05 ng/mL. If the Tg Ab is positive, Tg will be measured by tandem mass spectrometry. The LC/MS/MS assay will provide quantitative measurement of Tg in the presence of Tg Ab.

### Performed By Quest Diagnostics Nichols Institute

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Nichols Institute