New test - Thyroglobulin Reflex Panel

WHAT’S NEW?
Effective October 1, 2016, a new reflex panel will be available: Thyroglobulin, Serum/Plasma with Reflex to LC-MS/MS or CIA (order code LAB6764). This will replace Thyroglobulin Antibody & Thyroglobulin test, LAB4052.

INDICATIONS FOR ORDERING
This test is recommended for the surveillance of residual/recurrent thyroid cancer. It accurately measures thyroglobulin levels in serum or plasma.

BACKGROUND
Anti-thyroglobulin antibodies are commonly identified in 20-30% of patients with differentiated thyroid carcinoma. When present, they interfere with the immunometric measurement of thyroglobulin (Tg), which is the primary biochemical marker used for disease surveillance, creating challenges in monitoring patients for residual or recurrent disease.

Tg-IAs (immunoassays) remain the method of choice for Tg quantitation in TgAb negative patients. In TgAb negative patients with undetectable Tg by immunometric assay, the Tg-MS will detect Tg in up to 20% additional cases. The Tg-RIA will detect Tg in approximately 35% of cases, but a significant proportion of these will be clinical false-positive results. The undetectable Tg-MS seen in approximately 40% of TgAb negative cases in patients with disease need further evaluation.

(J Clin Endocrinol Metab 100:E1074–E1083, 2015)

The persistence of anti-Tg antibodies, especially if levels are rising, may indicate persistent, recurrent, or progressive thyroid cancer. In contrast, declining anti-Tg antibody levels may indicate reduced tumor burden or the absence of disease.

WHAT’S CHANGED?
This panel is built to address the accurate measurement of thyroglobulin in the presence of interfering thyroglobulin antibodies using the following algorithm.

Note: In this new reflex, thyroglobulin is measured using LC-MS/MS instead of RIA.

Thyroglobulin antibody is performed by Chemiluminescent Immunoassay on the Beckman Dxi (to rule out presence of interfering TgAb)

If Thyroglobulin antibody is negative, Thyroglobulin is performed by Chemiluminescent Immunoassay on the Beckman Dxi (Reflex#1) (if no interfering antibodies detected)

If Thyroglobulin Ab results are above the upper reference limit of 4.0 IU/mL, (Reflex#2) Thyroglobulin is performed by LC-MS/MS

LIMITATIONS
- Limit of detection with LC-MS/MS – 0.5 ng/mL
- Results obtained with different test methods or kits cannot be used interchangeably
- Thyroglobulin results, regardless of concentration, should not be interpreted as absolute evidence for the presence or absence of papillary or follicular thyroid cancer
- Not recommended for use as a screening procedure to detect the presence of thyroid cancer in the general population

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### ORDERING INFORMATION

**Reflex Panel, Thyroglobulin, Serum/Plasma with Reflex to LC-MS/MS or CIA (LAB6764)**

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Quantitative Chemiluminescent Immunoassay/High Performance Chromatography-Tandem Mass Spectrometry</th>
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</thead>
<tbody>
<tr>
<td>Performed</td>
<td>Daily</td>
</tr>
<tr>
<td>Released</td>
<td>1-7 days after receipt at reference laboratory</td>
</tr>
<tr>
<td>CPT</td>
<td>86800, 84432</td>
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</tbody>
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#### Specimen Requirements

<table>
<thead>
<tr>
<th>Collection</th>
<th>Serum separator tube (SST); Green (Na heparin)</th>
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<tbody>
<tr>
<td>Handling</td>
<td>Separate serum or plasma from cells within 2 hours of collection. Freeze.</td>
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<tr>
<td>Transport</td>
<td>Submit 3 mL frozen serum or plasma in transport tube.</td>
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<tr>
<td>Stability</td>
<td><strong>Frozen:</strong> 6 months <strong>Refrigerated:</strong> Unacceptable &gt;48 hours <strong>Ambient:</strong> Unacceptable &gt; 8 hours</td>
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<tr>
<td>Rejection</td>
<td>EDTA or K2EDTA plasma; any specimen other than indicated in collection instructions; specimens received exceeding temperature stability.</td>
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### QUESTIONS?

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