THYROID

ACCESS TSH (3rd IS) ASSAY FOR THYROID ASSESSMENT

Introduction

Thyroid stimulating hormone (TSH) is part of the hypothalamic-pituitary-thyroid axis that regulates the body’s metabolism. The hypothalamus secretes a thyrotropin-releasing hormone (TRH), leading to the secretion of TSH by the pituitary gland. TSH causes the thyroid hormones, T3 and T4, to be released, controlling metabolic functions within the cells. When excessive amounts of T3 or T4 circulate, production of TRH stops, resulting in the process being controlled by a negative feedback loop.1,2

TSH assays are classified by generation, based on functional sensitivity. Nearly all TSH assays in use are 3rd generation assays. Measurement of TSH aids in thyroid assessment and monitors thyroid replacement therapy. The National Academy of Clinical Biochemistry has recommended that the functional sensitivity of 3rd generation TSH assays be ≤0.02 µIU/mL.3

Access TSH (3rd IS) Assay Benefits

› Standardization to the World Health Organization (WHO) 3rd IS for human TSH (IRP 81/565) for greater confidence in test results
› Improved workflow: less hands-on time for the laboratory due to a larger reagent pack size (100 tests/pack, 200 tests per kit)
› Reliable and accurate results with an assay range that supports measuring patient samples as low as 0.01 µIU/mL

Assay Characteristics

Expected Values

A multicenter prospective study across geographically diverse locations using apparently healthy, euthyroid adults was conducted to establish a central 97.5% reference interval using the Access TSH (3rd IS) assay. This study included a general population of approximately equal numbers of males and non-pregnant females, and pregnant females, with approximately equal distribution across all three trimesters. Samples were analyzed following the CLSI EP28-A3c guideline.4 Each laboratory should establish its own reference intervals to ensure proper representation of specific populations.

<table>
<thead>
<tr>
<th>Population</th>
<th>Sample Size</th>
<th>Median (µIU/mL)</th>
<th>97.5% Reference Interval (µIU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Population (males and non-pregnant females, aged 21-88)</td>
<td>367</td>
<td>1.48</td>
<td>0.45 - 5.33</td>
</tr>
<tr>
<td>1st Trimester</td>
<td>318</td>
<td>1.13</td>
<td>0.05 - 3.70</td>
</tr>
<tr>
<td>2nd Trimester</td>
<td>362</td>
<td>1.47</td>
<td>0.31 - 4.35</td>
</tr>
<tr>
<td>3rd Trimester</td>
<td>335</td>
<td>1.61</td>
<td>0.41 - 5.18</td>
</tr>
</tbody>
</table>
Imprecision

Representative data for imprecision are provided for illustration only. Performance obtained in individual laboratories may vary. The Access TSH (3rd IS) assay exhibits total imprecision CV ≤10% at concentrations >0.02 µIU/mL and total standard deviation (SD) ≤0.0029 µIU/mL at concentrations ≤0.02 µIU/mL.

One study, using four serum-based samples on one UniCel DxI 800 Immunoassay System, generating a total of 40 assays—two replicates per assay—over 20 days with two runs per day, provided the following data, calculated based on CLSI EP5-A3 guidelines:6

Access TSH (3rd IS) Imprecision Results

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (µIU/mL)</th>
<th>Within Run SD (µIU/mL)</th>
<th>CV (%)</th>
<th>Between Day SD (µIU/mL)</th>
<th>CV (%)</th>
<th>Between Run SD (µIU/mL)</th>
<th>CV (%)</th>
<th>Total SD (µIU/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>0.02</td>
<td>0.0004</td>
<td>1.8</td>
<td>0.0008</td>
<td>3.7</td>
<td>0.0004</td>
<td>1.6</td>
<td>0.0010</td>
<td>4.4</td>
</tr>
<tr>
<td>Sample 2</td>
<td>0.37</td>
<td>0.006</td>
<td>1.5</td>
<td>0.010</td>
<td>2.7</td>
<td>0.006</td>
<td>1.5</td>
<td>0.013</td>
<td>3.5</td>
</tr>
<tr>
<td>Sample 3</td>
<td>4.71</td>
<td>0.13</td>
<td>2.7</td>
<td>0.11</td>
<td>2.4</td>
<td>0.008</td>
<td>0.2</td>
<td>0.17</td>
<td>3.6</td>
</tr>
<tr>
<td>Sample 4</td>
<td>38.76</td>
<td>1.36</td>
<td>3.5</td>
<td>1.80</td>
<td>4.6</td>
<td>0.49</td>
<td>1.3</td>
<td>2.31</td>
<td>5.9</td>
</tr>
</tbody>
</table>

Characteristics

- Sample Type/Size: Serum (gel and no gel) and plasma (lithium heparin)/55 µL
- Reportable Measuring Range: 0.01 to ~50.0 µIU/mL
- Limit of Detection (LoD): ≤0.005 µIU/mL
- Limit of Quantitation (LoQ) (≤10% between run CV): ≤0.01 µIU/mL
- Imprecision: Total imprecision ≤10% CV at TSH concentrations >0.02 µIU/mL; and total standard deviation ≤0.0029 µIU/mL at TSH concentrations ≤0.02 µIU/mL
- Open Pack Stability: 28 days
- Approximate Calibrator Levels: 0.050, 0.30, 3.0, 15.0 and 50.0 µIU/mL
- Calibration Stability: 28 days
- Time to First Result: 26 minutes (approximately)

Ordering Information

- Access TSH (3rd IS): 2 packs of 100 tests/pack
- Access TSH (3rd IS) Calibrators: S0-S5, 1 vial/level of 2.5 mL/vial

References