ACCESS 25(OH) VITAMIN D TOTAL FOR THE ACCESS 2 IMMUNOASSAY SYSTEM

DIAGNOSTIC CONFIDENCE IN 25(OH) VITAMIN D MEASUREMENT

INTRODUCTION

Vitamin D is a lipid-soluble steroid hormone that is essential to the maintenance of overall bone health because of its key role in maintaining calcium and phosphorus homeostasis. In adults, vitamin D deficiency can lead to bone pain, osteomalacia and proximal muscle weakness; in infants and children, deficiency can cause the bone deformation known as rickets.1,2 Emerging evidence suggests that vitamin D deficiency may also be associated with increased risk for cancer, infectious disease, cardiovascular disease, diabetes and other chronic diseases.1,3

Vitamin D exists in two primary forms, vitamin D3 (cholecalciferol) and vitamin D2 (ergocalciferol). Vitamin D3 is produced in the skin through the action of sunlight, while both vitamin D2 and D3 can be obtained from dietary sources or supplementation. In the body, vitamin D2 and D3 are converted to 25(OH) vitamin D which is the major circulating metabolite of vitamin D. Serum concentration of total 25(OH) vitamin D is considered the standard clinical measure of vitamin D status and reflects inputs from sources of both vitamin D2 and D3.4 There is currently debate over the optimal values of 25(OH) vitamin D in serum; however, many experts recommend that a level of ≥ 30 ng/mL (75 nmol/L) provides optimal health benefits.3,4

HOW ACCESS 25(OH) VITAMIN D TOTAL MOVES THE LAB FORWARD

› Confidence in patient results through standardization to the ID-LC-MS/MS Reference Measurement Procedure (RMP) from Ghent University.5,6
› Accurate clinical assessment of vitamin D status provided by measurement of total 25(OH) vitamin D with equimolar measurement of 25(OH) vitamin D2 and 25(OH) vitamin D3.
› Excellent stability and reproducibility combined with greater storage convenience from a unique, opaque reagent pack designed to prevent light-induced reagent degradation.
ACCESS 25(OH) VITAMIN D TOTAL

ASSAY STANDARDIZATION

The Access 25(OH) Vitamin D Total Calibrators are traceable to the Joint Committee for Traceability in Laboratory Medicine (JCTLM) approved isotope dilution mass spectrometry (ID-LC-MS/MS) reference measurement procedure (RMP) developed at Ghent University. This gold standard method is the reference procedure utilized by the Vitamin D Standardization Program (VDSP), an international collaboration established by the Office of Dietary Supplements at the National Institutes of Health, aimed at promoting standardized laboratory measurements of 25(OH) vitamin D around the world.

A comparison of 110 serum samples evaluated with the Access 25(OH) Vitamin D Total assay on the Access 2 Immunoassay System and this ID-LC-MS/MS RMP gave the following results using Passing-Bablok regression and Spearman correlation:

<table>
<thead>
<tr>
<th>N</th>
<th>Slope</th>
<th>Correlation Coefficient (r)</th>
<th>Units = ng/mL</th>
<th>Units = nmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Range of Observations</td>
<td>Intercept</td>
</tr>
<tr>
<td>110</td>
<td>1.01</td>
<td>0.95</td>
<td>8.0 - 98.6</td>
<td>-2.87</td>
</tr>
</tbody>
</table>

†Observed concentration range of the RMP.

CHARACTERISTICS

<table>
<thead>
<tr>
<th>Sample Type/Size</th>
<th>Serum, plasma (lithium heparin)/30 μL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reportable Measuring Range</td>
<td>7.0 to 120 ng/mL (17.5 to 300 nmol/L)</td>
</tr>
<tr>
<td>Limit of Detection (LoD)</td>
<td>2.0 ng/mL (5.0 nmol/L)</td>
</tr>
<tr>
<td>20% CV Limit of Quantitation (LoQ)</td>
<td>7.0 ng/mL (17.5 nmol/L)</td>
</tr>
<tr>
<td>Precision</td>
<td>Total imprecision ≤ 10.0% CV at concentrations &gt; 15.0 ng/mL (37.5 nmol/L), and total Standard Deviation (SD) ≤ 1.5 ng/mL (3.8 nmol/L) at concentrations ≤ 15.0 ng/mL</td>
</tr>
<tr>
<td>Open Pack Stability</td>
<td>28 days</td>
</tr>
<tr>
<td>Open Calibrator Stability</td>
<td>56 days</td>
</tr>
<tr>
<td>Calibration Stability</td>
<td>28 days</td>
</tr>
<tr>
<td>Time to First Result</td>
<td>39 minutes (approx.)</td>
</tr>
</tbody>
</table>

ORDERING INFORMATION

Access 25(OH) Vitamin D Total for Access 2
2 packs of 50 tests/pack | B24838

Access 25(OH) Vitamin D Total Calibrators for Access 2
S0-S5, 1 vial/level of 1.4 mL/vial | B24839

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References