VITAMIN D TESTING SIMPLIFIED

The First and Only
TWO REAGENT VITAMIN D ASSAY
FOR CLINICAL CHEMISTRY ANALYZERS

- Recognizes both Vitamin D2 & D3 equally
- Rapid throughput with an assay time <10 min, and reaches more than 500 tests/hr on the Roche Cobas c701
- No sample pre-treatments or pre-dilution steps required
- Low sample volume of 3 µL
- Good correlation to LC-MS/MS method
- No risk of biotin interference

- Certified by the CDC VDSCP Program
- Meets the performance target set by the DEQAS advisory panel
- Traces to NIST
- Excellent assay precision (%CV <5% at 30 ng/mL)
- Wide assay dynamic range (7.6 – 147.8 ng/mL)

510(k) Cleared; EU: CE, VD

DIAZYME
Innovations in Clinical Diagnostics
ASSAY SPECIFICATIONS

<table>
<thead>
<tr>
<th>Method</th>
<th>Latex Enhanced Immunoturbidimetric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Type &amp; Volume</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td>Sample Volume</td>
<td>3 μL</td>
</tr>
<tr>
<td>Method Correlation</td>
<td>N = 171</td>
</tr>
<tr>
<td></td>
<td>y-intercept = -3.03</td>
</tr>
<tr>
<td></td>
<td>Slope = 1.062</td>
</tr>
<tr>
<td></td>
<td>R² = 0.9575</td>
</tr>
<tr>
<td></td>
<td>Samples Ranged From: 8.4 - 146.8 ng/mL</td>
</tr>
<tr>
<td>Linearity</td>
<td>7.6 - 147.8 ng/mL</td>
</tr>
<tr>
<td>LOB</td>
<td>1.2 ng/mL</td>
</tr>
<tr>
<td>LOD</td>
<td>2.9 ng/mL</td>
</tr>
<tr>
<td>LOQ</td>
<td>7.6 ng/mL</td>
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<tr>
<td>Calibration Levels</td>
<td>5-Point Calibration</td>
</tr>
</tbody>
</table>

Diazyme EZ Vitamin D Assay Procedure

R1: 160 μL Sample: 3 μL

R2: 40 μL 700 nm

37°C 0 min 4 8 min

*Analyzer Dependent

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

ASSAY PRECISION

<table>
<thead>
<tr>
<th>Specimen</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
<th>SD</th>
<th>%CV</th>
<th>SD</th>
<th>%CV</th>
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</thead>
<tbody>
<tr>
<td>Control #1</td>
<td>80</td>
<td>21.7</td>
<td>0.9</td>
<td>3.9%</td>
<td>0.6</td>
<td>2.8%</td>
<td>1.3</td>
<td>6.2%</td>
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<tr>
<td>Control #2</td>
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<td>42.5</td>
<td>1.0</td>
<td>2.4%</td>
<td>0.8</td>
<td>2.0%</td>
<td>1.7</td>
<td>3.9%</td>
</tr>
<tr>
<td>Sample #1</td>
<td>80</td>
<td>22.1</td>
<td>0.8</td>
<td>3.8%</td>
<td>0.8</td>
<td>3.8%</td>
<td>1.2</td>
<td>5.6%</td>
</tr>
<tr>
<td>Sample #2</td>
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<td>42.8</td>
<td>0.9</td>
<td>2.0%</td>
<td>1.0</td>
<td>2.4%</td>
<td>1.3</td>
<td>3.1%</td>
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<td>Sample #3</td>
<td>80</td>
<td>99.5</td>
<td>1.8</td>
<td>1.8%</td>
<td>1.5</td>
<td>1.6%</td>
<td>2.7</td>
<td>2.8%</td>
</tr>
</tbody>
</table>

ASSAY METHOD COMPARISON

A comparison of the EZ Vitamin D assay (y) using samples measured with LC-MS/MS (x) gave the following correlation:

\[ y = 1.0297x - 0.813 \]
\[ R^2 = 0.9622 \]

A comparison of the EZ Vitamin D assay (y) using samples measured with a commercially available 25-hydroxyvitamin D immunoassay (x) gave the following correlation:

\[ y = 1.1537x - 1.2321 \]
\[ R^2 = 0.9716 \]

Conclusion: Diazyme EZ Vitamin D assay has a good correlation with a commercially available 25-hydroxyvitamin D immunoassay (R² > 0.97)

VITAMIN D DEFICIENCY & INTOXICATION


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