The LOCI Vitamin D Total (VITD) Assay for use on the Dimension® EXL™ system is a homogeneous competitive chemiluminescent immunoassay based on LOCI® technology. The assay measures the total 25(OH)vitamin D concentration [comprising both 25(OH)vitamin D$_2$ and 25(OH)vitamin D$_3$] in both serum and plasma.

**Outstanding Assay Performance**

- Provides excellent sensitivity for more accurate differential assessment of Vitamin D sufficiency for improved patient care
- Delivers fast turnaround time — 31 minutes time to first result
- Offers good reagent and calibrator stability to improve laboratory operational and labor efficiency with less hands-on time
- Allows opportunity for workload consolidation of routine and specialized tests for increased productivity
- Reduces interference with minimal (4%) cross-reactivity to 3-epi-25(OH)vitamin D$_3$

**Intended Use**

The LOCI Vitamin D Total Assay is for in vitro diagnostic use in the quantitative measurement of total 25(OH) vitamin D in human serum and plasma on the Dimension EXL integrated chemistry system with LOCI module. Measurements of vitamin D are used in the assessment of vitamin D sufficiency.

**Clinical Utility**

Vitamin D is a steroid hormone involved in the intestinal absorption of calcium and the regulation of calcium homeostasis. Vitamin D is essential for the formation and maintenance of strong, healthy bones. Vitamin D deficiency can result from inadequate exposure to the sun, inadequate alimentary intake, decreased absorption, abnormal metabolism, or vitamin D resistance.

While there are many metabolites of vitamin D, the total 25(OH)vitamin D, that is, the sum of 25(OH)vitamin D$_2$ and 25(OH)vitamin D$_3$, is the most reliable indicator of vitamin D status. Vitamin D$_2$ is derived from plant sources, whereas vitamin D$_3$ is derived primarily from the conversion of 7-dehydrocholesterol in the skin by UV-B radiation from sunlight and secondarily from animal sources.$^1$

For assay management, the consensus panel provides the following recommendations.$^3$

- Reported patient values should be a single total 25(OH)vitamin D assay reported in ng/mL, measuring both 25(OH)vitamin D$_2$ and 25(OH)vitamin D$_3$.
- Serum is the recommended sample type
- Refer to Instructions for Use for health and population based reference values.
- Although there is no consensus document on serum 25-hydroxyvitaminD level, most experts$^2,3$ agree that vitamin D sufficiency is above 30 ng/mL (75 nmol/L), an insufficient level is between 20 and 30 ng/mL (50 to 75 nmol/L), and a deficient level is any value below 20 ng/mL (50 nmol/L).
**Dimension EXL System—Optimizing Productivity**

Dimension EXL Integrated Chemistry Systems offer fast, easy-to-use versatility and proven outcomes.

- Fast and reliable results using trusted, proven technologies including LOCI® advanced chemiluminescence
- Automated, productivity-enhancing features, including proactive alerts, STAT sample loading in any position, and single-tube simultaneous sampling for both chemistry and immunoassays
- Test most critical laboratory assays with a comprehensive menu

**Standardization**

The assay is standardized using internal standards which are traceable to the ID-LC-MS/MS 25(OH)vitamin D Reference Measurement Procedure (RMP). The ID-LC-MS/MS RMP is traceable to the NIST SRM 2972.

**LOCI Vitamin D Total Assay Performance Summary**

<table>
<thead>
<tr>
<th>LOCI Vitamin D Total Assay</th>
<th>Sample Type</th>
<th>Sample Volume</th>
<th>Assay Range</th>
<th>Limit of Quantitation</th>
<th>Onboard Stability</th>
<th>Calibration Interval</th>
<th>TTFR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Serum, lithium heparin plasma, EDTA plasma</td>
<td>8 µL</td>
<td>5.0–150.0 ng/mL</td>
<td>5.0 ng/mL [12.5 nmol/L]</td>
<td>30 days</td>
<td>7 days</td>
<td>31 minutes</td>
</tr>
</tbody>
</table>

**Method Comparison**

Dimension EXL LOCI Vitamin D Total Assay Vs. Univ. of Ghent ID-LC-MS/MS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope (Passing Bablok)</td>
<td>1.06</td>
</tr>
<tr>
<td>Intercept (Passing Bablok)</td>
<td>0.4 ng/mL [1.0 nmol/L]</td>
</tr>
<tr>
<td>Pearson Correlation Coefficient (r)</td>
<td>0.977</td>
</tr>
<tr>
<td>n</td>
<td>163</td>
</tr>
<tr>
<td>Range</td>
<td>5.2–126.1 ng/mL [13.0–315.3 nmol/L]</td>
</tr>
</tbody>
</table>

**Ordering Information**

<table>
<thead>
<tr>
<th>10706480</th>
<th>Dimension EXL VITD Flex® Reagent Cartridge</th>
<th>200 test kit: 4 Flexes, 50 tests/Flex</th>
</tr>
</thead>
<tbody>
<tr>
<td>10711395</td>
<td>Dimension EXL VITD Calibrator Levels 1–5</td>
<td>10 vials: 2 vials per level; 2.0 mL per vial (Level 2); 1.5 mL per vial (Levels 1,3,4,5)</td>
</tr>
</tbody>
</table>