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Dimension EXL LOCI Vitamin D Total Assay Specifications

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 D₂ and 25(OH)vitamin D₃] 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 D₃

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.

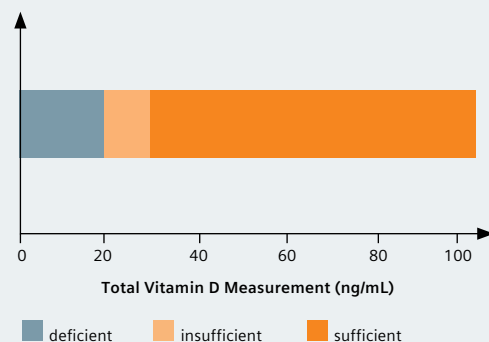
Clinical Utility

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 D₂ and 25(OH)vitamin D₃, is the most reliable indicator of vitamin D status. Vitamin D₂ is derived from plant sources, whereas vitamin D₃ 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.¹

- Reported patient values should be a single total 25(OH) vitamin D assay reported in ng/mL, measuring both 25(OH)vitamin D₂ and 25(OH) vitamin D₃.
- 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

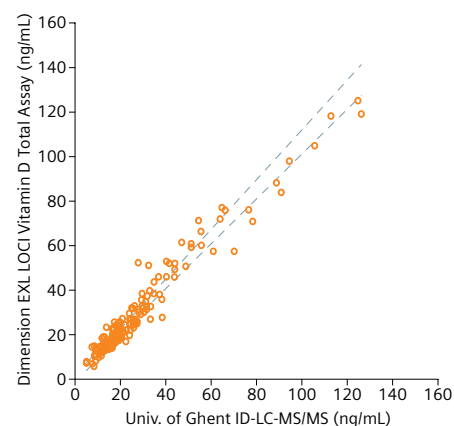
The assay is standardized using internal standards which are traceable to the ID-LC-MS/MS 25(OH)vitamin D Reference Measurement Procedure (RMP). The ID-LC-MS/MS RMP is traceable to the NIST SRM 2972.

LOCI Vitamin D Total Assay Performance Summary

	Sample Type	Sample Volume	Assay Range	Limit of Quantitation	Onboard Stability	Calibration Interval	TTR
LOCI Vitamin D Total Assay	Serum, lithium heparin plasma, EDTA plasma	8 µL	5.0–150.0 ng/mL [12.5–375.0 nmol/L]	5.0 ng/mL [12.5 nmol/L]	30 days	7 days	31 minutes

Method Comparison

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



Parameter	Result
Slope (Passing Bablok)	1.06
Intercept (Passing Bablok)	0.4 ng/mL [1.0 nmol/L]
Pearson Correlation Coefficient (r)	0.977
n	163
Range	5.2–126.1 ng/mL [13.0–315.3 nmol/L]

Ordering Information		
10706480	Dimension EXL VITD Flex® Reagent Cartridge	200 test kit: 4 Flexes, 50 tests/Flex
10711395	Dimension EXL VITD Calibrator Levels 1–5	10 vials: 2 vials per level; 2.0 mL per vial (Level 2); 1.5 mL per vial (Levels 1,3,4,5)

1. Souberbielle JC, et al. Autoimmunity Review. 2010;9:709–715.
2. Bischoff-Ferrari HA, et al. Am J Clin Nutr 2006;84:18-28.
3. Malabanan A, et al. Redefining vitamin D insufficiency. Lancet 1998;351:805-6

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