

25-HYDROXY VITAMIN D ASSAY

Micro-Titer Plate

Diazyme's 25-Hydroxy Vitamin D (EIA) Kit is a cost effective assay for use on both manual and automated microplate readers. The assay features a unique automated acetonitrile extraction step which removes interfering substances such as Vitamin D binding proteins and lipids, ensuring accurate and reliable results. The fully liquid stable system detects total Vitamin D levels (D2 + D3) and utilizes standards that are directly traceable to NIST SRM-972 reference material.

DIAZYME 25-HYDROXY VITAMIN D ASSAY ADVANTAGES

- Fast test results (<2 hours) for rapid throughput on a 96 well Dynex DS2 Micro-Titer plate processor
- Results display excellent correlations to LC-IDMS/MS methodology
- Automated extraction step removes interfering substances such as lipids and proteins thereby increasing assay accuracy
- Liquid stable format requires no reagent preparation, saving time and reducing sample handling
- The large change in optical density is one of the key reasons for the assay's outstanding analytical performance

REGULATORY STATUS

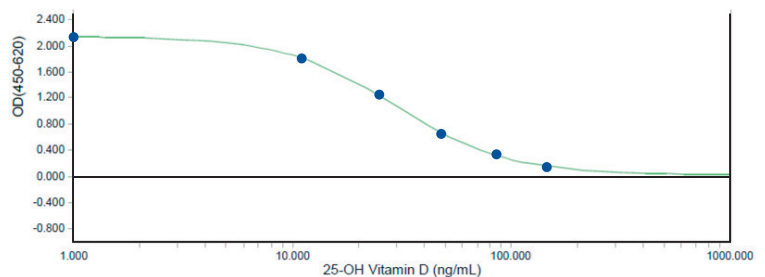
510(k) Cleared
Health Canada Registered



AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- Dynex
- DS2

*This assay is supported by an automated Micro-Titer Plate reader — Check with your Diazyme representative for other automated systems.



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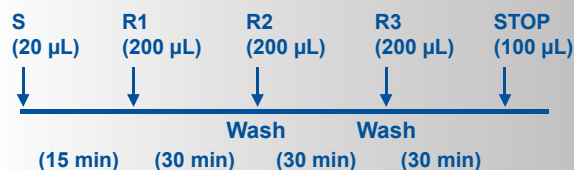
Micro-Titer Plate



ASSAY SPECIFICATIONS

Method	Extraction/Enzyme Immunoassay (EIA)
Sample Type & Volume	<ul style="list-style-type: none">• Serum• Plasma<ul style="list-style-type: none">- EDTA- Heparin Sample Volume 20 µL
Method Correlation	N = 58 y-intercept = 1.448 ng/mL Slope = 0.941 R2 = 0.930 Sample Range: 11.9 ng/mL - 131.5 ng/mL
Linear Range	8.3 - 143.6 ng/ml
LOB LOD LOQ	3.0 ng/mL 5.6 ng/mL 8.3 ng/mL
Calibration Levels	6-Point Calibration
Reagent On-Board Stability	Unopened: Stable when stored at 2-8°C until expiration date on the label Opened: 4 weeks when stored at 2-8°C

25-Hydroxy Vitamin D Assay Procedure for Automated Microplate Reader*



*Analyzer Dependent

Parameter questions for 25-Hydroxy Vitamin D Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

- Holick, MF. Vitamin D Status: Measurement, Interpretation and Clinical Application. *Ann Epidemiol.* 2009, 19(2): 73-78.
- National Osteoporosis Foundation. Prevention - Vitamin D. <http://www.nof.org/aboutosteoporosis/prevention/vitamind>

ASSAY PRECISION

Precision was evaluated according to the CLSI EP5-A guideline where each specimen was measured over a period of 20 days at the rate of two runs per day and two replicates per run. 10 serum samples and 2 serum controls were used in the study.

Specimen	n	Mean (ng/mL)	Within-run CV (%)	Total CV (%)
Control #1	80	26.0	3.7	6.0
Control #2	80	52.3	2.7	7.5
Sample #1	80	23.3	7.1	8.1
Sample #2	80	40.0	9.2	9.4
Sample #3	80	52.8	2.2	7.6
Sample #4	80	69.3	2.8	8.7
Sample #5	80	84.1	5.6	7.5
Sample #6	80	101.4	4.6	5.6
Sample #7	80	116.8	4.2	4.9
Sample #8	80	116.2	2.6	5.5
Low Sample #1	80	10.5	13.3	17.6
Low Sample #2	80	12.7	9.0	16.0

ASSAY INTERFERENCE

The following substances do not interfere with this assay at the levels tested (less than 10% basis):

Hemoglobin:	up to 500 mg/dL	Triglycerides:	up to 450 mg/dL
Bilirubin:	up to 40 mg/dL	Absorbic Acid:	up to 10 mM
Conjugated Bilirubin:	up to 40 mg/dL		

REFERENCE RANGE

To determine a reference range for the Diazyme 25-OH Vitamin D microplate assay, the 25-OH Vitamin D serum concentrations of a U.S. population of 157 apparently healthy individuals (ages between 21 and 80 years old), from three different geographical locations, were measured with the Diazyme method. This study yielded the following results:

- Lowest 25-OH Vitamin D concentration: 8.4 ng/mL
- Highest 25-OH Vitamin D concentration: 61.3 ng/mL
- Median 25-OH Vitamin D concentration: 29.1 ng/mL
- Observed range (2.5th to 97.5th percentile): 12.0 to 55.0 ng/mL

There is little universal agreement on the optimal concentration of 25-OH Vitamin D. Review of literature^{1, 2} suggests the recommendation for 25-OH Vitamin D levels are:

Level	Range
Deficient	<10
Insufficient	10-29
Sufficient	30-100
Potential Toxicity	>100

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