



VITAMIN D TESTING SIMPLIFIED



Vitamin
Marker

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 μ L
- 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:  

25-OH VITAMIN D ASSAY

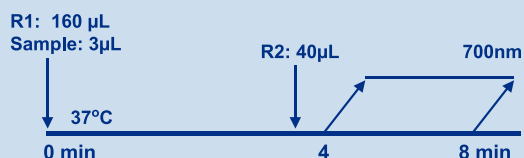
For Clinical Chemistry Analyzers

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	<ul style="list-style-type: none"> Serum Plasma <p>Sample Volume 3 μL</p>
Method Correlation	<p>N = 171</p> <p>y-intercept = -3.03</p> <p>Slope = 1.062</p> <p>R² = 0.9575</p> <p>Samples Ranged From: 8.4 - 146.8 ng/mL</p>
Linearity	7.6 - 147.8 ng/mL
LOB	1.2 ng/mL
LOD	2.9 ng/mL
LOQ	7.6 ng/mL
Calibration Levels	5-Point Calibration

Diazyme EZ Vitamin D Assay Procedure*



*Analyzer Dependent

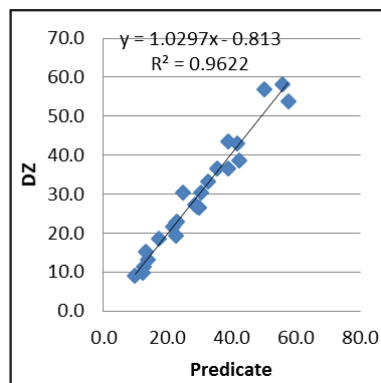
For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

ASSAY PRECISION

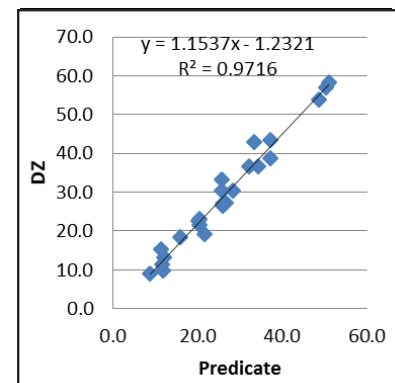
25-OH Vitamin D (ng/mL)	Within-Run		Between-Run		Total			
	Specimen	n	Mean	SD	%CV	SD	%CV	
Control #1	80	21.7	0.9	3.9%	0.6	2.8%	1.3	6.2%
Control #2	80	42.5	1.0	2.4%	0.8	2.0%	1.7	3.9%
Sample #1	80	22.1	0.8	3.8%	0.8	3.8%	1.2	5.6%
Sample #2	80	42.8	0.9	2.0%	1.0	2.4%	1.3	3.1%
Sample #3	80	99.5	1.8	1.8%	1.5	1.6%	2.7	2.8%

ASSAY METHOD COMPARISON

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

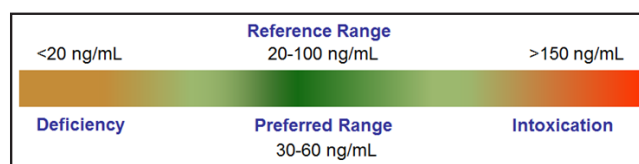


A comparison of the EZ Vitamin D assay (y) using samples measured with a commercially available 25-hydroxyvitamin D immunoassay (x) gave the following correlation:



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



2007 M. Holick, NEJM 357:3; 2007 J. Hathcock et.al Am J Clin Nutr. 85: 6

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