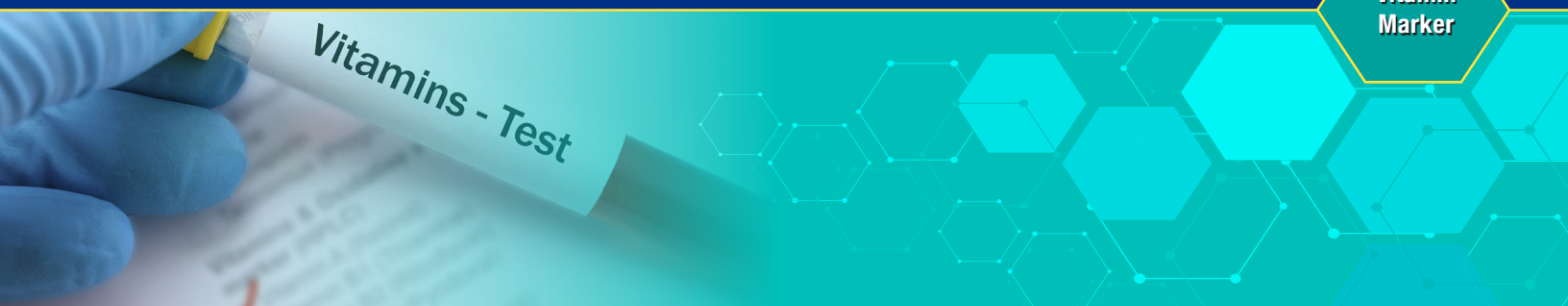


# VITAMIN D TESTING SIMPLIFIED


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  $\mu$ 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

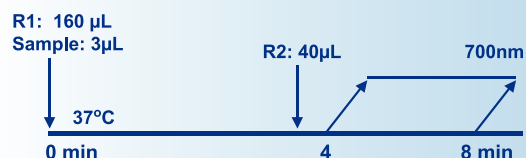
For Clinical Chemistry Analyzers

Dual Vial  
Liquid Stable

## ASSAY SPECIFICATIONS

<b>Method</b>	Latex Enhanced Immunoturbidimetric
<b>Sample Type &amp; Volume</b>	<ul style="list-style-type: none"> <li>Serum</li> <li>Plasma</li> </ul> <p>Sample Volume 3 <math>\mu</math>L</p>
<b>Method Correlation</b>	<p>N = 171</p> <p>y-intercept = -3.03</p> <p>Slope = 1.062</p> <p>R<sup>2</sup> = 0.9575</p> <p>Samples Ranged From: 8.4 - 146.8 ng/mL</p>
<b>Linearity</b>	7.6 - 147.8 ng/mL
<b>LOB</b>	1.2 ng/mL
<b>LOD</b>	2.9 ng/mL
<b>LOQ</b>	7.6 ng/mL
<b>Calibration Levels</b>	5-Point Calibration

### Diazyme EZ Vitamin D Assay Procedure\*



\*Analyzer Dependent

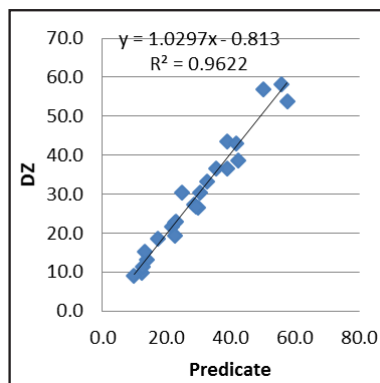
For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

## ASSAY PRECISION

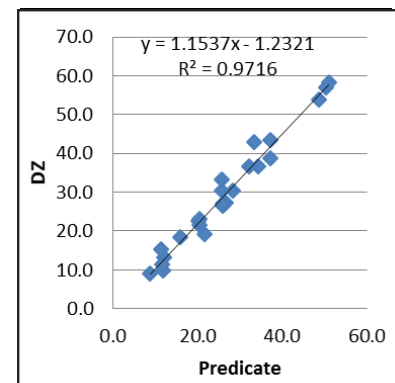
25-OH Vitamin D (ng/mL)			Within-Run		Between-Run		Total	
Specimen	n	Mean	SD	%CV	SD	%CV	SD	%CV
Control #1	80	21.7	0.9	3.9%	0.6	2.8%	1.3	6.2%
Control #2	80	42.5	1.0	2.4%	0.8	2.0%	1.7	3.9%
Sample #1	80	22.1	0.8	3.8%	0.8	3.8%	1.2	5.6%
Sample #2	80	42.8	0.9	2.0%	1.0	2.4%	1.3	3.1%
Sample #3	80	99.5	1.8	1.8%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

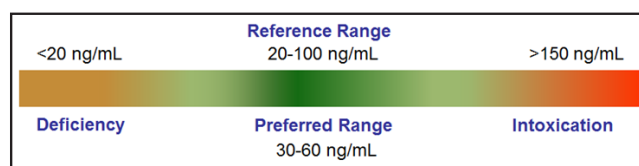


A comparison of the EZ Vitamin D assay (y) using samples measured with a commercially available 25-hydroxyvitamin D immunoassay (x) gave the following correlation:



**Conclusion:** Diazyme EZ Vitamin D assay has a good correlation with a commercially available 25-hydroxyvitamin D immunoassay (R<sup>2</sup> > 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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