DIAZYME

VITAMIN MARKER

25-OH VITAMIN D ASSAY

For Clinical Chemistry Analyzers

Three Vial Liquid Stable

Diazyme is the first to offer a liquid stable and cost effective 25-OH Vitamin D Assay designed to work on fully automated clinical chemistry analyzers. The highly accurate 25-OH Vitamin D assay detects total Vitamin D (D2 + D3) and is directly traceable to NIST SRM-972 standards. The assay is highly precise and has excellent correlation to LC-MS/ MS and other chemiluminescence assays. Each kit is supplied with a liquid calibrator set for added convenience. Controls are available separately.

DIAZYME 25-OH VITAMIN D ASSAY FOR CLINICAL CHEMISTRY ADVANTAGES

- Time to first result (15 – 19 Minutes)
- Results display excellent correlations to LC-MS/MS and leading 25-OH Vitamin D Immunoassays
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable format requires no reagent preparation, saving time and reducing sample handling

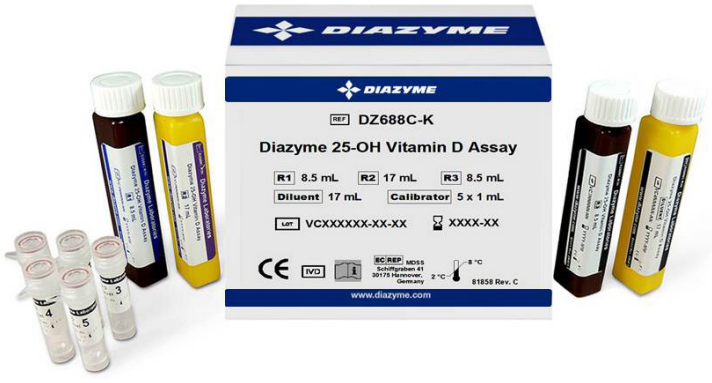
REGULATORY STATUS

510(k) Cleared Health Canada Registered CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**

  - Hitachi



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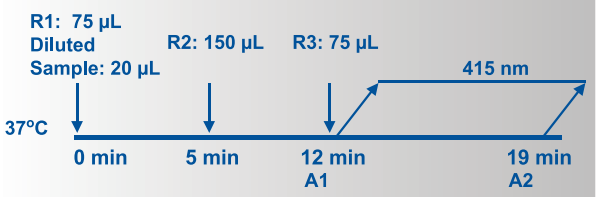
ASSAY SPECIFICATIONS

Method	FemtoQuant™ Enzyme Immunoassay
Sample Type & Volume	• Serum • Plasma - K_3-EDTA - Li-heparin Sample Volume 20 µL
Method Correlation	N = 98 y-intercept = -0.21 ng/mL Slope = 1.005 R^2 = 0.968 Sample Range: 9.5 ng/mL – 140.9 ng/mL
Linear Range	7.6 to 147.8 ng/mL
LOB ***LOD*** ***LOQ***	2.0 ng/mL 3.5 ng/mL 7.6 ng/mL
Calibration Levels	5-Point Calibration
Reagent On-Board Stability	Unopened: ≥ 8 months when stored at 2-8°C Opened: 4 weeks when stored at 2-8°C

*25-OH VITAMIN D ASSAY PROCEDURE FOR CLINICAL CHEMISTRY ANALYZERS**



***Analyzer Dependent**

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

ASSAY PRECISION

Precision was evaluated according to the CLSI EP5-A guideline. Controls and samples were measured daily over the span of 20 days, using three lots of reagents and one chemistry analyzer. 40 independent runs were performed on each specimen. Each run produced two measurements. 80 data points were obtained per specimen. Results are shown below:

25-OH Vitamin D (ng/mL)			Within-run		Between-run		Total	
Speciman	n	Mean	SD	CV%	SD	CV%	SD	CV%
Control #1	80	23.1	1.47	6.4	1.04	4.5	1.68	7.3
Control #2	80	45.7	2.06	4.5	1.67	3.7	2.12	4.6
Sample #1	80	22.6	1.19	5.3	1.11	4.9	1.45	6.4
Sample #2	80	31.7	1.42	4.5	1.59	5.0	1.81	5.7
Sample #3	80	40.6	1.42	3.5	1.59	3.9	1.66	4.1
Sample #4	80	48.6	2.32	4.8	1.71	3.5	2.41	4.9
Sample #5	80	55.8	2.14	3.8	1.73	3.1	2.34	4.2
Sample #6	80	65.4	2.03	3.1	1.79	2.7	2.42	3.7
Sample #7	80	69.7	2.02	2.9	1.99	2.9	2.55	3.7
Sample #8	80	92.8	2.52	2.7	2.02	2.2	3.40	3.7
Sample #9	80	134.6	2.97	2.2	2.69	2.0	3.87	2.9
Low Sample #1	80	9.4	1.22	13.0	0.98	10.4	1.31	14.0
Low Sample #2	80	11.2	1.58	14.2	0.88	7.9	1.55	13.9

ASSAY INTERFERENCE

Interference studies were conducted according to the CLSI EP7-A2 guideline. The acceptance criterion was set at 10% or less deviation between the spiked sample and the control. The assay's results were not significantly affected by the following substances:

Substance	Concentration	Substance	Concentration
Conjugated Bilirubin	40 mg/dL	Ampicillin	1000 ng/mL
Free Bilirubin	40 mgldL	Cyclosporine C	105 ng/mL
Hemoglobin	100 mg/dL	Cefoxitin	660 ng/mL
Ascorbic Acid	176 mg/dL	Acetylsalicylic Acid	1000 ng/mL
Triglycerides	750 mg/dL	Rifampicin	64 ng/mL
Uric Acid	20 mg/dL	Acetaminophen	200 ng/mL
Biotin	2 mg/dL	Ibuprofen	500 ng/mL
Human Serum Albumin	9 g/dL	Theophylline	100 ng/mL
N-Acetyl Cysteine Amide	1663 ng/mL		

Cross-reactivity of the Diazyme 25-OH Vitamin D Assay was determined by adding Vitamin D metabolites to serum pool samples. Based on the results in the table below, the assay did not cross react with Vitamin D2 and Vitamin D3 and the assay recovers both 25-OH Vitamin D2 and 25-OH Vitamin D3 similarly. Cross-reactivity with various Vitamin D metabolites is summarized in the table below:

Compound	Concentration tested	Cross-reactivity
25-OH Vitamin D3	44.0 ng/mL	100%
25-OH Vitamin D2	44.0 ng/mL	92.3%
Vitamin D3	44.0 ng/mL	1.0%
Vitamin D2	44.0 ng/mL	2.9%
1,25-(OH)2 Vitamin D3	2.9 ng/mL	2.5%
1,25-(OH)2 Vitamin D2	2.9 ng/mL	-1.5%
24R,25-(OH)2 Vitamin D3	41.0 ng/mL	5.1%
3-epi-25-OH Vitamin D3	42.0 ng/mL	61.7%
3-epi-25-OH Vitamin D2	42.0 ng/mL	55.1%

**%Cross-reactivity = (Corrected Assay Value/Concentration Spiked)*100*

No significant cross-reactivity (4.1%) was found for Paricalcitol (Zemplar®) up to 25 ng/mL.

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