



25 (OH) VITAMIN-D ELISA

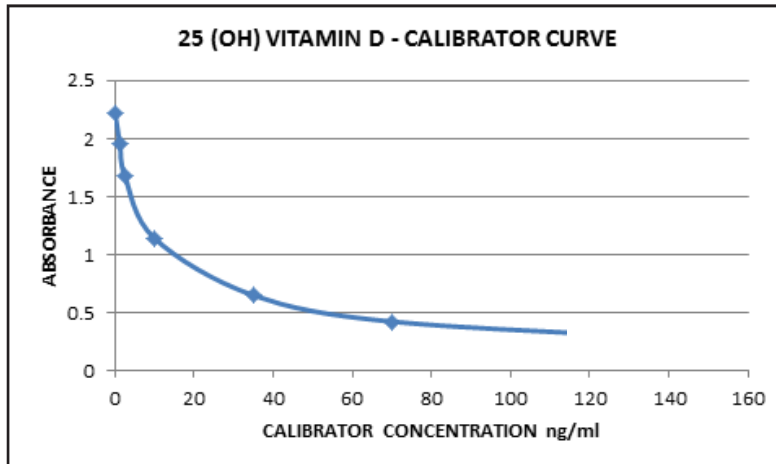
TOTAL TURNAROUND TIME (90 MINUTES)

FEATURES	ADVANTAGES	BENEFITS
Solid Phase enzyme linked immunoassay with a 90 min turnaround time.	Can be applied on most of the immunoassay systems available in the market.	Assay is universal. Need for special equipment eliminated.
100 % cross reactivity with D2 and D3.	Accurate indication of Vitamin D Status.	State of the art. Single assay gives information about the overall status.
No Extraction step for samples	Eliminates organic solvents and preserves sample conformity.	Eliminates additional step and increases more results in shorter times.
Excellent precision in manual and automated systems.	Excellent Intra and Inter assay precision.	Robust construction of the assay and excellent component wise assay build.
Excellent method correlation with LC/MS/MS.	Excellent specificity.	Ensures that results are specific to the measurand tested.
Calibrators traceable to NIST SRM-927A.	Follows international standardization recommendations.	Ensures traceable and commutable results.
Most sensitive Elisa kit available with a 1.25 ng/ml limit of quantitation.	Excellent lower limit of detection.	Eliminates unnecessary repeats and thereby is more economical than most commercially available Elisa assays.

25 (OH) VITAMIN-D ELISA - TECHNICAL SPECS

Typical Calibration Curve:

CAL ID	CAL CONC (ng/ml)	ABSORBANCE	QC TEST	CRITERIA	ACTUAL
A	0	2.70	Abs (A)	>2.000	2.23
B	5.8	2.45	B/A	<0.9	0.88
C	15	2.10	C/B	<0.9	0.86
D	29	1.69	D/C	<0.75	0.68
E	59	1.22	E/D	<0.75	0.57
F	113	0.45	F/E	<0.75	0.65



Precision:

Intra assay precision was worked out in a manual Elisa system with 20 replicates of each level of control material.

CONTROL	MEAN	SD	CV%
Vitamin D Level 1	8.969 ng/ml	0.556	6.20 %
Vitamin D Level 2	60.91 ng/ml	0.994	1.63%

Inter Assay Precision:

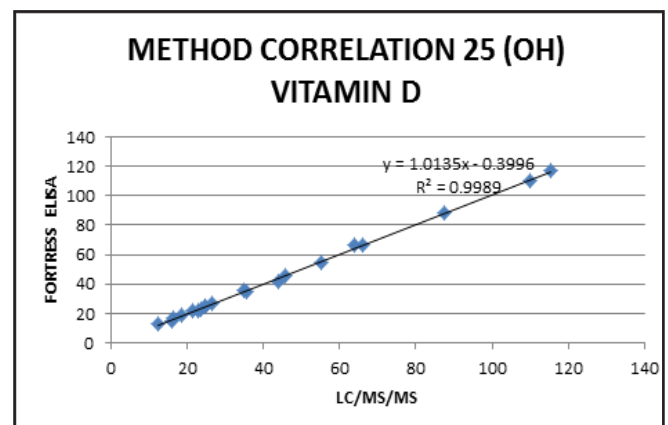
Inter assay precision was worked out in a manual Elisa system with 10 replicates of each level of control material.

CONTROL	MEAN	SD	CV%
Vitamin D Level 1	8.96 ng/ml	0.462	5.5 %
Vitamin D Level 2	60.9 ng/ml	0.750	1.9 %

Method Comparison:

Method comparison assays were carried out by running 20 samples in the Fortress Elisa and compared with the values from LC/MS/MS.

SAMPLE ID	LC/MS/MS	FORTRESS
1	21.5	22.3
2	18.4	18.7
3	16.3	16.8
4	15.9	14.9
5	115.3	116.9
6	109.8	110.4
7	87.6	88.4
8	35.4	34.7
9	65.9	66.3
10	45.7	45.8
11	23.6	22.7
12	34.7	35.6
13	43.9	41.4
14	12.4	12.9
15	55.1	54.7
16	63.7	66.5
17	24.8	24.7
18	26.3	26.8
19	24.7	25.3
20	22.9	21.8



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