

Reagents for STAT LAB T Analyzer & Auto Chemistry Analyzer

25 -OH Vitamin D

REF: 399 001 **25 Tests** R1: 1 x 4.1 ml R2: 1 x 1.1 ml
REF: 399 002 **50 Tests** R1: 1 x 8.1 ml R2: 1 x 2.1 ml
REF: 399 003 **200 Tests** R1: 1 x 32 ml R2: 1 x 8 ml

Intended Use

The testing of Vitamin D in serum is an important tool for physicians and individuals to determine whether individual is Vit. D deficient or not

Background

The role of vitamin D in regulating circulating levels of calcium and phosphorus to ensure normal bone mineralization is well known. Emerging evidence correlates insufficient levels of vitamin D to an increased risk of developing non-skeletal pathologies: cardiovascular diseases, hypertension, cancer, diabetes, multiple Sclerosis, rheumatoid arthritis, infectious diseases.

The diverse effects of vitamin D are mediated by receptors that regulate more than 200 genes. Besides the receptors present in the intestine and the bone, vitamin D Receptors have been identified in brain, prostate, breast, colon, immune cells, vascular smooth muscle and cardiomyocytes plus 17 types of cancers and Alzheimer's and Depression.

Test Principle

Vitamin D Assay kit is a direct particle-enhanced immunoturbidimetric assay. The assay's proprietary reagents are designed to dissociate vitamin D from vitamin D binding proteins, found in serum or plasma specimens, while particles coated with antivitamin D antibodies bind to the dissociated vitamin D, thereby causing agglutination.

This agglutination is detected as an absorbance change (700 nm), Specimen concentrations of Total Vitamin D are determined by interpolation from a 5 point calibration curve prepared from calibrators of known concentrations.

Reagents

R1: Phosphate buffer solution (< 100 mM), 0.1% sodium azide.

R2: Suspension of latex particles (< 0.5%) coated with anti- vitamin D antibodies, ready to use.

Additional Reagents

Calibration Set of 5 different levels available upon request.











Storage and Stability

Store all reagents refrigerated at 2-8°C. Unopened reagents are stable up to the expiration date printed on the labels. Opened vials are stable for one month.

Sample preparation

Serum, K₂-EDTA plasma, K₃-EDTA plasma or Li-heparin plasma samples can be used for the assay.

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Use by/Expiration Date
	For in-vitro diagnostic use		CAUTION. Consult instructions for use
	Batch Code/Lot number		Manufactured by
	Catalogue Number		(Xi) - Irritant
	Consult instructions for use		
	Temperature Limitation		

Precautions

1. The reagent is for in vitro diagnostic use only.
2. Reagents are liquid stable, ready-to-use reagents. Mix by inverting at least 10 times before use.
3. Do not mix reagents of different lots.
4. **DO NOT FREEZE.**
5. All human specimens should be regarded as potentially Bio-hazardous. Therefore, universal precautions should be used in specimen handling.

Procedure

Wavelength	680 - 700 nm
Method	fixed rate
Temperature	37°C

For STAT LAB T Analyzer

	Calibrator	Sample
R1 (μL)	160	160
Calibrator(μL)	5	-
Sample (μL)	-	5
Mix and incubate for 4 minutes exactly, then add R2		
R2(μL)	40	40
Read the absorbance (A1) Immediately After 4 minutes, read absorbance (A2)		

For Auto Chemistry Analyzer

	Calibrator	Sample
R1 (μL)	120	120
Calibrator(μL)	4	-
Sample (μL)	-	4
Mix and incubate for 4 minutes exactly, then add R2		
R2(μL)	30	30
Read the absorbance (A1) Immediately After 4 minutes, read absorbance (A2)		

Calculation

Generate a reference calibration curve using Vitamin D calibrators, Determine (Δ A) Sample and each calibrator:

(Δ A) Sample= A2-A1 sample

(ΔA) Calibrator = A2-A1 for each calibrator

Plot the calibration curve and obtain the results.

*Note: for semi-auto chemistry analyzers please adjust the test by double the volumes.

Expected values

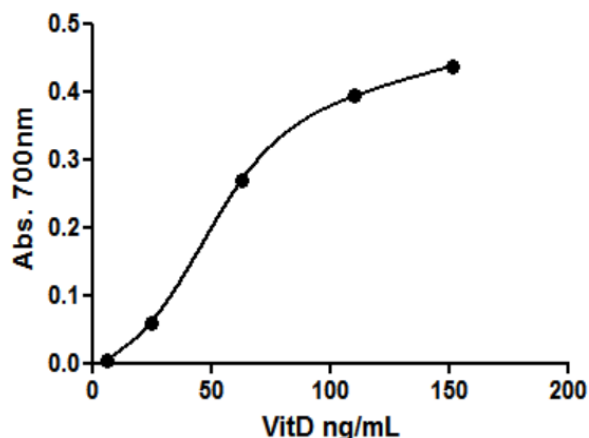
Level	Reference Range
Deficient	< 7.4 ng/ml
Insufficient	7.4 ng/ml – 20 ng/ml
Sufficient	20 ng/ml – 40 ng/ml
Therapeutic	50 ng/ml – 100 ng/ml
Intoxication	> 100 ng/ml

Calibration curve for Statlab T :

Calibrator ng/ml	Absorbance
5	-0.018
20	0.022
55	0.088
98	0.127
152	0.153

Note:
Each laboratory should establish its own calibration Curve
The given values can only be an average indication.

Vitamin D calibration curve



Performance characteristic

- Sensitivity** 5 ng/ml
- Analytical Range:** Between 5 and 160 ng/mL.
- Correlation:** A study using 40 human specimens between this procedure and reference method yielded a correlation coefficient of 0.9874 and a linear regression equation of $y = 1.021x + 0.014$
- Precision:**
Precision was established by assaying samples with different vitamin D levels twenty times each, results are shown in the following table;

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	11.1	0.9	8.3%	0.5	4.4%	1.8	16.6%
Sample #2	80	18.2	0.9	4.9%	0.7	3.9%	1.6	8.7%
Sample #3	80	22.1	0.8	3.8%	0.8	3.8%	1.2	5.6%
Sample #4	80	42.8	0.9	2.0%	1.0	2.4%	1.3	3.1%
Sample #5	80	59.5	1.0	1.7%	0.7	1.2%	1.6	2.7%
Sample #6	80	80.2	1.3	1.6%	1.1	1.4%	2.0	2.5%
Sample #7	80	99.5	1.8	1.8%	1.5	1.6%	2.7	2.8%
Sample #8	80	117.6	2.2	1.9%	2.0	1.7%	3.7	3.2%
Sample #9	80	139.2	2.7	1.9%	2.6	1.8%	4.1	2.9%

Interferences

Substance	Tolerance	Unit
Free bilirubin	40	mg/dL
Conjugated bilirubin	40	mg/dL
Hemoglobin	600	mg/dL
Total protein	12.0	g/dL
Triglycerides	1000	mg/dL
Rheumatoid Factor (RF)	200	IU/mL

Reference:

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Egyptian Company for Biotechnology (S.A.E)

Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.

Tel: +202 4489 2248 - Fax: +202 4489 2247

www.spectrum-diagnostics.com

E-mail:info@spectrum-diagnostics.com



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



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