

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

Background

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

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

Deficient
Insufficient
Sufficient
Therapeutic
Intoxication

Reference Range

< 7.4 ng/ml
7.4 ng/ml – 20 ng/ml
20 ng/ml – 40 ng/ml
50 ng/ml – 100 ng/ml
> 100 ng/ml

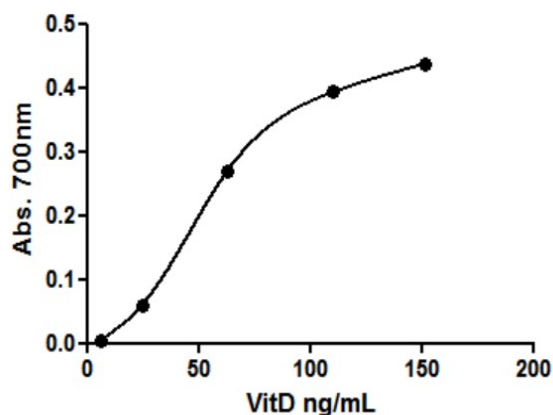
Calibration curve for Statlab T :

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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