VITAMIN D
(Latex-Enhanced Immunoturbidimetry Method)

Intended Use

A Vitamin D Test reagent/kits medical device intended for the estimation of Vitamin D in serum/plasma.

Principle

When the 25-hydroxy Vitamin D in the sample binds to the latex-coated anti-vitamin D antibody in the reagent, an antigen-antibody complex forms, producing certain turbidity. The level of turbidity is proportional to the amount of antigen in the presence of a certain amount of antibody. The quantitative determination of 25-hydroxy vitamin D can be performed by measuring turbidity at a wavelength of 630 nm and using a multi-point calibration curve.

Clinical Significance

Vitamin D is an indispensable trace element in the human body. A large number of studies have shown that with age, the blood pressure increase of people who are deficient in vitamin D is 20% higher than that of people with sufficient Vitamin D; people with low Vitamin D levels has much higher risk to develop their first cardiovascular accidents within 5 years and their cardiovascular disease mortality is double that of people with sufficient Vitamin D.

Adequate Vitamin D levels can effectively reduce the risk of colon tumors, breast tumors, and ovarian tumors. At the same time, studies have confirmed that Vitamin D levels are positively correlated with insulin sensitivity, and the incidence of type 2 diabetes is negatively correlated with Vitamin D levels. It can be seen that ensuring adequate Vitamin D levels can reduce the risk of type 2 diabetes. In addition, Vitamin D can also regulate gene expression and further regulate immune cells. Vitamin D receptor (VDR) polymorphisms and serum Vitamin D status are both closely associated with the risk of autoimmune diseases such as multiple sclerosis (IMS), type I diabetes, systemic lupus erythematosus (SLE), and rheumatoid arthritis (RA).

Kit Contents

1. R1 – Buffer Solution
2 .R2 – Latex Solution
3. Calibrator Liquid Form. (Ready to use)

Reagent Storage & Stability

Store the reagent at 2-8°C. Do not freeze.

The shelf life of reagents and calibrators is as per the expiry date mentioned on the respective bottle/vial labels.

Specimen Collection & Preservation

Serum, Plasma (Heparin or EDTA)

Sample should be stored at 2-8°C for 2 days or -20°C for longer period.

Discard the contaminated sample.

Manual Procedure

Wavelength	630 nm (600-670 nm)
Temperature	37°C

R1 Volume	480 µl
Sample/Calibrator Volume	9 µl
Mix well, incubate at 37°C for 5 min, then add	
R2 Volume	120 µl
Mix and aspirate the assay mixture. The first reading should be recorded at 30 sec (A1) followed by second reading after 210 sec (A2) at 37°C, 630 nm.	

Assay Guidelines for Analyzers System Parameters:

Mode	Fixed Time
Reaction Slope	Increasing
Wavelength	630 nm (600-670 nm)
Path Length	10 mm
R1 Volume	160 µl
Sample/ Calibrator Volume	3 µl
Incubation temperature	37°C
Incubation Time	5 min at 37°C
R2 Volume	40 µl
Flow Cell Temperature	37°C
Delay Time	30 sec
Read Time	210 sec
Linearity	165.0 ng/mL
Sensitivity	0.1 ng/mL

Calculation

Calculate and plot ΔA = (A2-A1) of the calibrators versus assigned concentration values on a linear graph paper. Calculate ΔA optical densities of samples and read values in ng/mL on the reference curve. Samples yielding absorbance above highest calibrator should be retested after further dilution.

Quality Control

For internal quality control any normal and abnormal controls should be assayed with each batch of samples.

Each laboratory should establish corrective action in case of deviations in control recovery.

Reference Values

Deficiency	: Less than 10 ng/mL
Insufficiency	: 10-30 ng/mL
Desirable	: 30-100 ng/mL
Toxic	: Greater than 100 ng/mL

It is recommended for each laboratory to establish its own

reference ranges for local population. 357:266-81

Performance Characteristics

1. **Measuring Range:** The test has been developed to determine Vitamin D within measuring range from 0.1-165.0 ng/mL
2. **Linearity:** The higher detection limit is up to 165.0 ng/mL. If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% w/v NaCl solution and reassayed. Multiply the result by dilution factor.
3. **Sensitivity:** The lower detection limit is up to 0.1 ng/mL
4. **Specificity/Interferences:** No interference by Total protein ≥ 12.0 g/dL, Free Bilirubin ≥ 40 mg/dL, Conjugated Bilirubin ≥ 40 mg/dL, Hemoglobin ≥ 600 mg/dL, Triglycerides ≥ 1000 mg/dL
5. **Precision:**

Intra-assay n=20	Mean (ng/mL)	SD	CV (%)
Sample 1	30.0	2.0	6.7
Sample 2	51.0	3.6	7.0

Inter-assay n=20	Mean (ng/mL)	SD	CV (%)
Sample 1	31.0	2.0	6.5
Sample 2	67.3	3.6	5.3

Waste Management

Please refer to local legal requirements.

Literature

1. Jones G. Vitamin D. In: Ross AC, Caballero B, Cousins RJ, Tucker KL, Ziegler TR, eds. Modern Nutrition in Health and Disease, 11th ed. Philadelphia: Lippincott Williams & Wilkins, 2014.
2. Institute of Medicine, Food and Nutrition Board. Dietary Reference Intakes for Calcium and Vitamin D. Washington DC: National Academy Press, 2010.
3. Brooks SPJ, Sempos CT. The importance of 25-hydroxyvitamin D assay standardization and the Vitamin D Standardization Program. Journal of AOAC International 2017; 100-1223-4
4. Holick MF, Vitamin D deficiency. N Engl J Med 2007;

Symbols

IVD	In Vitro Diagnostics	Caution	
LOT	Batch No.	Product Expiry Date	
CONT	Content	Manufactured By	
Read Instructions		Date of Manufacture	
Storage Temperature		Keep Dry	
REF	Catalogue No.	Fragile	
		Keep away from sun light	

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