

Vitamin D Estimation Kit

High-Q 25-Hydroxy Vitamin D (Ver.3)

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

Intended Use

For the quantitative determination of total 25-hydroxy vitamin D Total (D2 & D3) in human serum in vitro, and it is mainly used in the auxiliary diagnosis of 25-OH-Vitamin D deficiency related diseases.

Clinical Significance:

Vitamin D is a steroid hormone involved in the active intestinal absorption of calcium and in the regulation of its homeostasis. Vitamin D has two forms: Vitamin D2 and Vitamin D3. Vitamin D2 is obtained from dairy products whereas Vitamin D3 is produced in the skin after exposure to ultraviolet light. In the liver, Vitamin D is hydroxylated at its carbon 25 to form 25-OH Vitamin D. This metabolite is the pre-dominant circulating form of Vitamin D and is considered to be an accurate indicator of the general Vitamin D status of an individual. Vitamin D deficiency has been linked to many diseases including osteoporosis, rickets, and osteomalacia. Both dietary supplements of Vitamin D are currently available in the market (Vitamin D2 and Vitamin D3) and are converted to 25-OH Vitamin D in the liver. The sum of the concentrations of 25-OH Vitamin D2 and 25-OH Vitamin D3, in serum or plasma, is referred to as "Total 25-OH Vitamin D". Accurate monitoring of total 25-OH Vitamin D level is critical in clinical settings

Assay Principle:

25-hydroxy Vitamin D in the sample combines with the anti vitamin D antibody coated on latex in the reagent to form an antigen-antibody complex, which produces a certain turbidity. The turbidity is proportional to the content of antigen and the turbidity can be measured at the wavelength of 630 nm.

Presentation

Reagent 1:

10mM sodium phosphate, 2.7mM KCl, 137mM NaCl, 0.1% sodium azide, <0.1mg/mL

Reagent 2:

Latex Particles coated with Vitamin D Antibodies

All the reagents are stable till the expiry period stated on the labels

Calibrator:

Four level calibrators are provided in High -Q Vitamin D (Version -2). Calibrators are available as ready to use liquid stable calibrators and no reconstitution required. Calibrators are stable up to the expiry date mentioned on the labels.

Controls: (Optional)

Two level controls are available optionally in High -Q Vitamin D (Version -2). Controls are available as ready to use liquid stable controls and no reconstitution required. Controls are stable up to the expiry date mentioned on the labels.

Specimen Collection and Handling

Fresh and non-hemolysis serum. 25-hydroxy Vitamin D in the sample can be stable for 3 days at 2-8°C and for 1 month at -20°C in the frozen condition

Assay Procedure

Procedure Parameters: Four Level Calibration:

Reagent	Calibrator	Sample
Reagent 1	450 µl	450 µl
Calibrators (1,2, 3,4)	10 µl	----
Serum Sample	-----	10 µl

Mix. Incubate for 5 minutes at 37°C. This incubation step is a must to be followed

Reagent 2	50 µl	50 µl
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Mix and aspirate in to the analyzer immediately. Incubate for 10 Seconds (Delay) at 37°C and read the absorbance (A1) 240 Seconds later read the absorbance (A2).

Calculations:

$$\text{Concentration of Vitamin D in the sample} = \frac{A2-A1 (\text{Sample})}{A2-A1 (\text{Calibrator})} \times \text{Calibrator Conc.}$$

System Parameters:

Calibration Method	:	Spline/ Multipoint-Non Linear
Reaction Type	:	Fixed Time / Two Point
Reaction Direction	:	Increasing
Sample Volume	:	10 µl
Working Reagent Volume	:	R1 450 µl + R2 50 µl
Wave Length	:	630 nm (600-700)
Calibrators Conc.	:	On the label (Lot Specific)
Flow Cell Temp.	:	37°C
Linearity	:	250 ng/mL
Zero setting with	:	Distilled Water
Delay	:	10 Sec
Measuring	:	240 Sec

Quality control:

High-Q Vitamin D Controls are recommended for daily quality control. The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Reference Range:

30.0 - 100.0 ng/mL.

Interpretation:

Deficient	Less than 20
Insufficient	20 - 30
Sufficient	30 to 100
Toxicity	Greater than 100

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- **Explanation of the Results:** The testing results are affected by age, gender, location, etc. In general, the results are considered normal if they are within the reference range. Sources say that 76% of the Indian population suffers from vitamin D deficiency. Young adults below 25 age are seriously affected

Limitations of the detection method:

1.If the sample contains the following concentrations of interfering substances, there is no significant effect on the detection results:

- Bilirubin $\leq 20\text{mg/dL}$,
- Hemoglobin $\leq 2\text{g/L}$,
- Triglyceride $\leq 270\text{mg/dL}$,
- Ascorbic acid $\leq 20\text{mg/dL}$,
- Fat Emulsion $\leq 750\text{mg/dL}$,
- Rheumatoid factor $\leq 100\text{IU/mL}$.

2.The test results of the reagent are for clinical reference only and cannot be used alone as a basis for diagnosing or excluding cases. For diagnostic purposes, these results should be used in conjunction with clinical examination, medical history, and other examination results.

Performance Characteristics .

Linearity:

- The assay is linear between 8.0-250.0 ng/mL,
- Within the range of 8.0 to 60.0 ng/mL, the CV is within 15%
- Within the range of 60.0 to 150.0] ng/mL, the CV is within 5%

Accuracy:

The International standard Substance for 25-Hydroxy Vitamin D (NIST SRM972) was tested and repeated for 3 times, with the relative deviation of test results not exceeding $\pm 15\%$.

- 3.LOB: $\leq 5\text{ng/mL}$.
- 4. Precision: $\text{CV} \leq 10\%$; $R \leq 15\%$.

Precautions

1. For in-vitro diagnostic use only.
2. Reagents of different batches should not be mixed or used interchangeably.
3. After replacing the batch number, calibration should be re-determined.


















**Pariksha
Biotech**
A game changer in IVD

Product Features

- ❖ Latex Enhanced Turbidimetric Immuno Assay
- ❖ Liquid Stable Two Reagents
- ❖ Liquid Stable four calibrators provided
- ❖ Measurement at 630 nms (600 - 700 nms)
- ❖ Test Procedure time 9 minutes at 37°C
- ❖ Linearity : 250 ng/mL.
- ❖ Adaptable to Semi and Automated Analyzers

Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry Keep away from rain
	Catalog Number		

