25-Hydroxy Vitamin D Diagnostic Reagent Kit (Latex-enhanced Immunoturbidimetry Method) Product Instruction

Product name
Generic Name: 25-Hydroxy Vitamin D Diagnostic Reagent Kit (Latex-enhanced Immunoturbidimetry Method)
Abbreviation: 25-OHD

Package Specifications

R1	R2
20ml×1	5ml×1
40ml×1	10ml×1
80ml×2	20ml×2

Calibrator (liquid):
Specification 1 (1.0mL×6; 6 levels);
Quality control (liquid):
Specification 1 (1.0mL×2; 2 levels).

Intended use
25-Hydroxy Vitamin D Diagnostic Reagent Kit is used for quantitative in vitro determination of 25-Hydroxy Vitamin D in human serum on photometric systems.

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 (MS), type I diabetes, systemic lupus erythematosus (SLE), and rheumatoid arthritis (RA).

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 a 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 700 nm and using a multi-point calibration curve.

Main ingredient

Name	Ingredient	Concentration
R1	Phosphate buffer	＜100 mmol/L
	Sodium chloride	131mmol/L
	Perfluorohexanoic acid	＜1%
	Methanol	＜10%
	Preservative	0.5g/L
R2	Bovine serum albumin	0.1g/L
	Phosphate buffer	＜100 mmol/L
	Latex-coated anti-25-hydroxyvitamin D antibody	＜0.5%
	preservative	1g/L

Storage and stability
This kit stays stable for 18 months when stored in a dark condition at 2-8°C (do not freeze). After being opened for the first time, the kit can be stored at 2-8°C in an anti-pollution environment and stays stable for 30 days.

Specimen preparation
Fresh serum.
2-8°C, stable for 3 days.
-20°C, stable for 1 month.

Assay procedure
1. Reagent preparation
This reagent is liquid and can be used directly.

Main wavelength	700nm	Sample	3μl
Subwavelength	none	Reagent 1	160μl
Reation temperature	37°C	Reagent 2	40μl
Cuvette light path	1cm	Reaction type	Two Point End
Calibration method	Multi	Reaction direction	Increasing

2. Operation steps

Add to the cuvette:	
Sample (S)	3μl
R1	160μl

Mix well, incubate at 37°C for 5 minutes, then add	
R2	40µl
Mix well, incubate at 37°C for 30 seconds, absorbance A1; incubate at 37°C for 210 seconds, absorbance A2 △A= A2- A1	

Calculations

$$\text{Conc.Vitamin D} = \frac{\text{A(sample)- A(blank)}}{\text{A(Cal.) - A(blank)}} \times \text{Conc. Cal.}$$

Reference interval

30-100 ng/mL

It is recommended that each laboratory should establish its own reference interval.

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.

Performance characteristics

1. Measuring range:

8 - 150ng/mL

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

2. Sensitivity:

When the sample concentration is 60ng/mL, its absorbance (ΔA) should be ≥ 0.0100.

Interference

Bilirubin ≤40mg/dL, hemoglobin ≤500mg/dL, intralipid ≤3‰ do not affect the test results. In order not to affect the test results, please pay special attention by the operation.

Automation

Special adaptations for automatic analyzers can be made on request.

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.

Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameters for analyzers

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	19-30
Wave Length Sec	—
Wave Length Prim	700
ABS. Limit	32000
Sample Volume（uL）	3
R1 Volume（uL）	160
R2 Volume（uL）	0
R3 Volume（uL）	40
Calibration Type	SPLINE
Calibration Point	5
Span Point	3
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	3
Sample DIL. VOL.	/
R1 Volume（uL）	160
R2 Volume（uL）	40
Reagent DIL. VOL.	/
Measure Wave 1	700
Measure Wave 2	—
METHOD	END
SLOPE	-
Method Point	12-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-

OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Dynamic Range L	0
Dynamic Range H	150
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	5AB
Formula	spline
STD(1) Conc.#	*
Unit	ng/ml

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