25-Hydroxy Vitamin D Assay Kit (25-OH VD)

Method: Immunoturbidimetric

INTENDED USE

The Vitamin D assay is intended for use in clinical laboratories for the quantities determination of 25-OH vitamin D in human serum and plasma.

CLINICAL SIGNIFICANCE

Vitamin D, also known as anti rickets vitamins, belongs to fat soluble vitamins. Vitamin D, which oxidated by the monooxygenase system exists in liver microsomes, forms 25-hydroxy vitamin D, and it is the main form of circulation in the metabolism of vitamin D, can reflect the level of vitamin D [1]. Vitamin D deficiency can predispose children to rickets, which can lead to osteoporosis. In addition, the lack of vitamin D is also closely related to autoimmune diseases, infectious diseases and cardiovascular diseases. But long-term intake of excessive vitamin D will cause hypercalcemia and high urinary calcium. Characterized by anorexia, excessive thirst, nausea, vomiting, irritability, weakness, and diarrhea. Therefore, the detection of vitamin D levels in clinical has a very important significance[2,3].

ASSAY PRINCIPLE

While particles coated with anti-vitamin D antibodies bind to the 25-OH vitamin D in serum or plasma specimens, thereby causing agglutination lead to the changes of the absorbance. Through the establishment of the function relation of the absorbance and the standard concentration of 25-OH vitamin D, the 25-OH vitamin D levels of the samples can be determined.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris Buffer	0.1mol/L
Reagent 2 (R2)	
Suspension of latex particles	0.2%

SAMPLE COLLECTION AND PREPARATION

Serum and plasma samples can be used for the 25-OH vitamin D Assay.

STABILITY AND PREPARATION OF REGENTS

Collect whole blood by venipuncture and allow clotting. For plasma, mix the sample by gentle inversion prior to centrifugation. Centrifuge and separate serum or plasma as soon as possible after collection. The specimens may be refrigerated at 2-8℃ for two weeks. For long term storage, they can be stored at -20℃. Avoid repeated freeze-thaw cycles.

Do not use hemolysed serum or plasma samples. Allow the refrigerated or frozen-thawed samples to equilibrate to room temperature for 30 minutes before use; samples must be mixed well before analysis. Leaving specimens at room temperature for several hours will result in decay.

ASSAY PROCEDURE

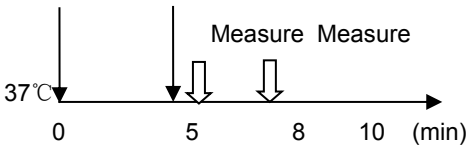
Test Procedure for Analyzers (HITACHI 7180)

Assay Mode: 2 Point End 18-29

Wave Length (main/sub): 700 nm/mm

Sample: 3 µl

R1: 160 µl R2: 40 µl



1. Mix 3 µl sample with 160 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 40 µl R2 into cuvette, Read initial absorbance A1 after 30 seconds and end absorbance A2 after 240 seconds.
3. Calculate absorbance change (ΔA=A2-A1)

CALIBRATION

Recommend that this assay should be calibrated using Gcell Calibration.

CALCULATIONS OF RESULTS

$$\text{Concentration} = \frac{\Delta A_{\text{sample}}}{\Delta A_{\text{calibrator}}} \times \text{calibrator value}$$

QUALITY CONTROL

Gcell quality control are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE[4].

Range (ng/mL)	Level of Vitamin D
<10	Deficiency
10-29	Insufficient
30-100	Sufficient
>100	Potential Toxicity

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

Linear range [8, 150] ng/ml, the linear correlation coefficient r should be≥0.990, in [8, 60] ng/ml range, the mesured linear deviation should be no more than ±9 ng/ml, in [60, 150] ng/ml range, the mesured linear deviation should be no more than ±15%.

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PRECISION

The CV of the test should be CV <10%

Intar assay precision		
N=20	level 1	level 2
Mean(ng/ml)	20.73	40.65
SD	0.81	0.96
CV(%)	3.92	2.36

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(ng/ml)	20.56	21.09	20.23
$\bar{x}$	20.63		
(Xmax-Xmin)/$\bar{x}$	0.042		

INTERFERENCE

The reagent can be used only for the determination of serum and plasma of the patients, if 25 (OH) vitamin D concentrations is higher than 160 ng/ml, the result is only > 150 ng/ml. Clinicians should consider all of the other factors for the explanations which may lead to the result, and the patient's clinical manifestations.

The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin up to 500 mg/dL
Triglyceride up to 1000 mg/dL
Bilirubin up to 40 mg/dL
Ascorbic Acid: up to 10 mM

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

[1] Holick MF. Vitamin D deficiency. N Engl J Med 2007;357:266–81.
[2] Wang T J et al. Vitamin D deficiency and risk of cardiovascular disease.circulation 2008;117;503-511.
[3].Holick, MF. Vitamin D Status: Measurement, Interpretation and Clinical Application. Ann Epidemiol. 2009, 19(2): 73–78.
[4] National Osteoporosis Foundation.Prevention – VitaminD.http://www.nof.org/aboutosteoporosis/prevention/Vitamin D.

INDEX OF SYMBOLS


Manufacture


Catalogue Number


Lot number


Date of manufacture


Use by(Expiration date)


For In-Vitro Diagnostic use only

Stored at 2-8℃


Attention:See instruction for use

Authorized Representative in the European Company

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