ACCUTURB-100

25-Hydroxy Vitamin D

Latex-Enhanced Turbidimetry Assay.

INTENDED USE

For the Quantitative determination of 25-Hydroxy Vitamin D in Serum/Plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	CONT
TVD 10T	1 x 2.6 ML
TVD 25T	1 x 6.3 ML
TVD 50T	1 x 12.5 ML

CLINICAL SIGNIFICANCE

Vitamin D helps your body absorb calcium and maintain strong bones throughout your entire life. Your body produces vitamin D when the sun's UV rays contact your skin. Other good sources of the vitamin include fish, eggs, and fortified dairy products. It's also available as a dietary supplement.
Vitamin D must go through several processes in your body before your body can use it. The first transformation occurs in the liver. Here, your body converts vitamin D to a chemical known as 25-hydroxyvitamin D, also called calcidiol.
The 25-hydroxy vitamin D test is the best way to monitor vitamin D levels. The amount of 25-hydroxyvitamin D in your blood is a good indication of how much vitamin D your body has. The test can determine if your vitamin D levels are too high or too low.
The test is also known as the 25-OH vitamin D test and the calcidiol 25-hydroxycholecalcifoerol test. It can be an important indicator of osteoporosis (bone weakness) and rickets (bone malformation).

PRINCIPLE

Latex particles coated with anti human 25-Hydroxy Vitamin D antibodies can agglutinated when mixed with samples containing 25-Hydroxy Vitamin D. The agglutination causes an absorbance change dependent upon the 25-Hydroxy Vitamin D contents of samples that can be quantified by comparison from a calibrator of known 25-Hydroxy Vitamin D concentration.

KIT CONTENT

Reagent	25 tests/kit	50 tests/kit	Major ingredients
Reaction buffer (R1 reagent)	1×5ml	1×10ml	Phosphate Reaction buffer
anti human 25-Hydroxy Vitamin-D antibodies coated latex combo (R2 reagent)	1×1.3ml	1×2.5ml	Latex particles coated with anti human 25-Hydroxy Vitamin-D antibodies
Cuvette & Bead	25 no's	50 no's	/
Specification	1 copy	1 copy	/
Magnetic card	1 piece	1 piece	/

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only.
2. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the anti human 25-Hydroxy Vitamin-D antibodies Reagent Material Safety Data Sheet.
3. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
4. Do not use the reagent after the expiration date printed on the kit.
5. Components from human origin have been tested and found to be negative for the presence of HBsAg,HCV and antibody to HIV(1/2).However handle the calibrator cautiously as potentially infectious material.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum or plasma: Stable for 7 days at 2-8°C.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolysed or lipemic sample.

REAGENT STABILITY

All the component of the kit are stable until the expiry date on the label when stored tightly closed at 2-8°C and contaminants prevented during there use, Do not use expired reagents.

ASSAY PROCEDURE

1.THE REAGENT DOSE DISPENSING IN THE CUVETTE

Reagent	Dose
Reaction Buffer (R1 Reagent)	200µl
Sample	5 µl
Mix and incubate for 4 minutes at 37°C	
anti human 25-Hydroxy Vitamin-D antibodies coated latex combo (R2 Reagent)	50µl

2. OPERATING STEP

(1). When starting it shows "Read card", Put the corresponding lot magnetic card in the reader slot, reading the card correctly, the screening displays the reagent name and lot number, the instrument status indication light is working (yellow-green). Please check carefully.
(2). After confirm the lot number, dispense 200µl reaction buffer (R1) to a colorimetric cuvette and 5µl sample and mixing sticker. Do not produce bubbles when dispensing the sample. Mix and incubate for 4 minutes at 37°C in incubator slot (A,B,C,D).
(3). Put the colorimetric cuvette in the detection well, gently press the cuvette until it contacts the bottom. The status indication light will be off when the analyzer detects the colorimetric cuvette successfully.
(4). When the analyzer shows "Add [R2]", dispense 50µl anti human 25-Hydroxy Vitamin-D antibody latex combo (R2) in the cuvette. The analyzer will mix automatically and start to detect, it shows: "Testing…" it shows the result automatically and record the value.
(5). After detecting, move the cuvette. The status indication light will be working (yellow- green). Return to step (2) to detect next sample.
(6). If moving the cuvette out in the process of detecting, the screen shows "Give up testing".
(7). If the result shows >130.00ng/ml, may use Normal saline to dilute the sample 1:5 (add 400µl Normal saline in 100µl sample), input dilution multiply 5, the analyser can calculate the sample concentration automatically.

LINEARITY

The method is linear to a concentration of 5 -130 ng/ml.
If the concentration exceeds this value, the sample should be diluted 1:5 with 0.9% saline solution and re-assayed.

REFERENCE INTERVAL

Deficiency	< 20 ng/ml.
Not enough	21 – 29 ng/ml
Enough	30 – 100 ng/ml
Potential toxicity	>100 ng/ml

QUALITY CONTROL

To ensure adequate quality control, Normal and abnormal control with assayed values should be run as unknown samples.

INTERFERENCES

Hemoglobin 600 mg/dL, Bilirubin 40 mg/dL and Lipemia 1000 mg/dL do not interfere. Other substances may interfere.

BIBLIOGRAPHY

1. Holick MF. Vitamin D status: measurement, interpretation and clinical application. Ann Epidemiol, 2009, 19(2): 73 - 78
2. Bikle DD Vitamin D and the skin. J. Bone Miner. Metab., 2010, 28, 117 - 30.
3. Zerwekh JE. Blood Biomarkers of Vitamin D status. Am. J. Clin. Nutr., 2008, 87:1087 - 1091

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