CE

25-(OH)VD Rapid Test Kit

Instructions for use | IVD | For in vitro diagnostic use only.

REF | A02019002 | Σ | 25 Tests

【Product Name】

25-(OH)VD Rapid Test Kit

【Intended Use】

The 25-(OH)VD Rapid Test Kit along with Anbio FIA Meter is a fluorescence immunoassay for quantitative measurement of 25-hydroxyvitamin D (25-(OH)VD) in human whole blood, serum or plasma. It is mainly used for the auxiliary diagnosis of vitamin D deficiency related diseases.

For professional use only.

【Summary】

25-hydroxyvitamin D(25-(OH)VD) is the main form of vitamin D in vivo. Vitamin D is a steroid derivative, which belongs to fat soluble vitamin. Vitamin D is mainly synthesized by human skin after ultraviolet irradiation, and a small part is taken from food or supplements. Vitamin D not only affects the metabolism of calcium and phosphorus, but also has a wide range of physiological functions. It is an essential substance to maintain human health, cell growth and development, and is closely related to a variety of diseases. There are two forms of vitamin D in human body, vitamin D3 (cholecalciferol) and vitamin D2 (ergocalcitol). Vitamin D is converted into 25-(OH)VD by hydroxylation in liver, and then into active 1,25-dihydroxyvitamin D in kidney. The level of 25-(OH)VD in blood can reflect the storage level of vitamin D in human body, and it is related to the clinical symptoms of vitamin D deficiency. More and more epidemiological and laboratory evidences show that serum 25-(OH)VD level is related to rickets, osteoporosis, Parkinson's disease, cardiovascular disease, hypertension, chronic kidney disease, type 2 diabetes and tumor in children. Therefore, the detection of 25-(OH)VD is very important for the diagnosis and prevention of related diseases.

【Test Principle】

The Anbio 25-(OH)VD Rapid Test Kit is based on fluorescence immunoassay technology. The Anbio 25-(OH)VD Rapid Test Kit uses a sandwich immuno detection method. When sample is added to the sample well of the test, the fluorescence-labeled detector 25-(OH)VD antibody binds to 25-(OH)VD antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and 25-(OH)VD are captured to anti-25-(OH)VD antibody that has been immobilized on test strip. Thus the more 25-(OH)VD antigen in the blood specimen, the more fluorescence-labeled antibody are accumulated on test strip. Signal intensity of fluorescence detector antibody reflects amount of 25-(OH)VD captured and Anbio FIA Meter shows 25-(OH)VD concentrations in blood specimen.

【Main Components】

The following components are included in the 25-(OH)VD Rapid Test Kit:

Supplied Materials:

Component	Main Ingredients
Test Cartridge	1) T line: Mouse anti-25-(OH)VD monoclonal antibody (coated) 2) C line: Goat anti-rabbit IgG polyclonal antibody 3) Binding pad: Fluorescent microsphere-labeled mouse anti-25-(OH)VD monoclonal antibody (labeled) and fluorescent microsphere-labeled rabbit IgG polyclonal antibody
IC Card	/
Sample Diluent	10mmol/L PBS

Optional Materials:

1. Sterile lancets (for Fingerstick Whole Blood only)
2. Alcohol pads (for Fingerstick Whole Blood only)
3. Disposable pipettes (10+50μL)

Materials Required but not Provided:

1. Transfer Pipette Set
2. Specimen Collection Containers
3. Centrifuge (for Plasma/Serum only)
4. Timer
5. Anbio FIA Meter (model number: AF-100, AF-100s, AF-1200, AF-100C)

【Storage Conditions and Shelf Life】

Component	Storage- Temperature limitation	Stability
Test Cartridge		The shelf life is up to 24 months. Please refer to use-by date on the label. Test Cartridge should be used within 1 hour after opening the pack.
IC Card		/
Sample Diluent		The buffer is stable up to 24 months. Please refer to use-by date on the label.

【Warnings and Precautions】

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with IC Card # that is inserted onto the equipment.
5. The Anbio 25-(OH)VD Rapid Test Kit is only operational in the Anbio FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector diluent tubes for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector diluent tubes should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

【Specimen Collection and Preparation】

The test can be performed with serum or plasma or whole blood.The plasma and whole blood samples are recommended to use EDTA, heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.

For Serum and Plasma:

1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

For Whole Blood Collected by Venipuncture:

1.Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant.
2.It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3.It's not suitable to test the whole blood samples storing at 2℃～8℃ for more than 2 days.

For Fingertip Whole Blood Samples:

1.Clean the puncture site with the alcohol pad.
2.After the alcohol is dried, the fingertips are punctured with safety Lancet to form blood droplets.
3.Lay the disposable pipettes, do not squeeze, automatically collect fingertip whole blood for 10μL.
4. It is recommended that specimens should be tested immediately.

【Test Procedure】

Refer to Anbio FIA Meter Operation Manual (attached to Anbio FIA Meter) for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1: Preparation

Check/ Swipe the IC Card information to the equipment.

Make sure the sample diluent is at the bottom of the tube by tapping or flicking before using.

Step2: Sampling

Draw 10μL of serum/plasma/whole blood with a transfer pipette and add it to the diluent tube.

Step3: Mixing

Close the lid of diluent tube and mix the specimen by shaking or tapping 6-8 times, until the specimen completely mixed. Let it stand 1 minute and then finish loading within 15 minutes.

Step4: Loading

Take 50μL of sample mixture with a transfer pipette and load it into the sample well of the Test Cartridge.

Step5: Testing

Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click "Timing Test". 15 minutes later, the result will show in the display and print out when click "Print".

Quick test: Put the Test Cartridge on the operation platform.15 minutes later, insert the Test Cartridge onto the

Test Cartridge Holder and click “Quick Test”. The result will show in the display and print out when click “Print”.

【Limitations of Procedure】

1. This test has been developed for testing human whole blood, serum and plasma specimen.
2. The results of Anbio 25-(OH)VD Rapid Test Kit should be evaluated with all clinical and laboratory data available. If 25-(OH)VD test results do not agree with the clinical evaluation, additional tests should be performed.
3. Incorrect results can be caused by interference from some similar substance in the sample.
4. Other factors may interfere with Anbio 25-(OH)VD Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

【Quality Control】

Internal procedural controls are included in the test. When testing, the quality control line (C line) will show a certain luminescence intensity, which is an internal procedural control. It confirms that a sufficient volume of samples has been added and that the correct procedure has been performed.

【Interpretation of Results】

The Anbio FIA Meter calculate the test result automatically and displays 25-(OH)VD concentration of the test sample in terms of ng/mL.

1. Conversion Factors:

ng/mL x 2.50 = nmol/L

2. The Reference Value Measured in an Apparently Healthy Population

8～56ng/mL

3. Health Based Reference Values (Recommended for Use):

Currently there is no standard definition of the optimal vitamin D status.Many specialists consider the commonly used population based reference values too low. Health based reference values are recommended to replace population based reference value.The US National Kidney Foundation considers levels < 30 ng/mL to be insufficient or deficient[2].The preferred level for 25-(OH)VD by many experts is now recommended to be ≥ 30 ng/mL[3].

Note: Individual reference range is suggested to be established for each laboratory.

【Performance Characteristics】

Limits and Range

Limit of Detection: 5.0ng/mL;

Limit of Quantitation:10.0ng/mL;

Measuring Range: 10.0-100.0ng/mL;

Precision

Precision was determined with Anbio test kits, samples, and controls according to the CLSI (clinical and Laboratory Standards Institute) protocol (EP05- A3):

(1)3 batches of test kits, repeated 10 times per batch (n=30).

ng/mL	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV	SD	CV	SD	CV	SD	CV
29.71	2.58	8.71%	2.37	8.04%	2.47	8.25%	2.40	8.07%
80.04	7.77	9.79%	6.08	7.67%	6.76	8.31%	6.74	8.42%

(2) 3 laboratories with duplicate testing 5 times a day for 5 days (n = 75).

ng/mL	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV	SD	CV	SD	CV
29.96	2.30	7.68%	2.31	7.71%	2.31	7.71%
79.43	6.31	7.94%	6.31	7.94%	6.57	8.27%

Limitations-Interference

Detection of the effects of the following endogenous substances on assay performance. Interfering substances detected in the listed concentration range had no effect on the results.

Compound	Concentration
Bilirubin	350 μmol/L
Triglycerides	40 mmol/L
Hemoglobin	2 g/L
RF	1500 IU/mL
HAMA	1000 ng/mL
Antinuclear antibody	1:640

Limitations-Cross-Reactivity

The following substances do not interfere with the 25-(OH)VD test results at the indicated concentrations.

Cross material	Concentration
1,25-dihydroxyvitamin D_3	100 ng/mL
1,25-dihydroxyvitamin D_2	100 ng/mL
Vitamin D_3	1000 ng/mL
Vitamin D_2	1000 ng/mL

【Bibliography of Suggested Reading】

1. KWAK H S, CHUNG H J, CHO D H, et al. Efficacy of the measurement of 25- hydroxyvitamin D2 and D3 levels by using PerkinElmer liquid chromatography-tandem mass spectrometry vitamin D kit compared with DiaSorin radioimmunoassay kit and Elecsys vitamin D total assay[J] . Ann Lab Med, 2015, 35 (2) 263-265.
2. KDOQI Clinical Practice Guidelines for Bone Metabolism and Diseasein Children With Chronic Kidney Disease. http://www.kidney.org/PROFESSIONALS/kdoqi/guidelines-pedbone/guide8.htm
3. Holick MF. Vitamin D status: measurement, interpretation, and clinicalapplication. Ann Epidemiol 2009;19(2):73-78.

【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
EC REP	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
30°C 2°C	Temperature limit	LOT	Batch code
	Use-by date		Keep dry
	Keep away from sunlight	REF	Catalog number
	Date of manufacture	Σ	Contains sufficient for <n> tests
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

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