25-（OH）VD Rapid Quantitative Test

For in vitro diagnostic use only. For professional use only.

INTENDED USE

The 25-（OH）VD Rapid Quantitative Test along with Anbio FIA Meter is intended for vitro quantitative determination of 25-（OH）VD in human whole blood, serum or plasma, it is mainly used for the auxiliary diagnosis of vitamin D deficiency related diseases..

SUMMARY

2-hydroxyvitamin D 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 hydroxyvitamin D25 - (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) d 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.

Normal Reference Value: 30～100ng/mL;

AND PRINCIPLE OF THE PROCEDURE

The Anbio 25-（OH）VD Rapid Quantitative Test is based on highly specific immune competition reaction principle and fluorescence immunochromatography technology to detect the content of 25 - (OH) VD in human blood. The kit contains 25 - (OH) VD conjugates fixed on the membrane test area (T) in advance, and 25 - (OH) VD monoclonal antibody labeled on the marker binding pad in advance. During the test, the sample enters the sample adding area. If the sample contains 25 - (OH) VD, it will react with the 25 - (OH) VD monoclonal antibody on the marker pad to form a complex. In the test area (T), the unbound fluorescent marker reacts with BSA-25 - (OH) VD conjugate fixed on the membrane to form a complex. Because 25 - (OH) VD in the sample competes with 25 - (OH) VD BSA coupling in the test area (T), the higher the content of 25 - (OH) VD in the sample, the more complex formed, thus the weaker luminescent intensity in the test area.

STORAGE AND STABILITY

1. Store the detector buffer at 2～30℃. The buffer is stable up to 18 months.
2. Store Anbio 25-（OH）VD Rapid Quantitative Test Cartridge at 4～30℃, shelf life is up to 18 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

Materials Supplied

- Test Cartridge
- Test Cartridge ID Chip
- Detector buffer

MATERIALS REQUIRED BUT NOT PROVIDED

- Transfer Pipette Set (10μL, 100μL size)
- Specimen Collection Containers
- Sterile Lancets(for Fingerstick Whole Blood only)
- Alcohol Pads
- Centrifuge (for Plasma/Serum only)
- Timer

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 ID Chip # that is inserted onto the equipment.
5. The Anbio 25-（OH）VD Rapid Quantitative 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. TheTest 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 buffer vials for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector buffer vials 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.

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 (EDTA recommended)
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 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℃.

TEST PROCEDURE

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

Step1: Preparation

Check/ swipe the ID Card information to the equipment.

Step2: Sampling

Draw 20 μL of whole blood or 15 μL of serum/plasma with a transfer pipette and add it to the buffer tube.

Step3: Mixing

Mix well the specimen with buffer for 1 minute by tapping or inverting the tube.

Step4:Loading

Take 100 μL of sample mixture and load it onto 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 Quantitative Test should be evaluated with all clinical and laboratory data available. If hs25-（OH）VD test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. EDTA other than anticoagulants (e.g. heparin or citrate) is suggested to use for plasma.
5. Other factors may interfere with Anbio 25-（OH）VD Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Detection Limit : 5.0ng/mL ;
Linear Range: 5.0-120.0ng/mL;
Linear correlation coefficient R ≥ 0.990;
Precision: within batch C.V. is ≤ 15%; between batches C.V. is ≤ 20%;
Accuracy: the relative deviation of the measurement results shall not exceed ± 15% when the standardized accuracy calibrator is tested.

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..

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