25(OH)VD Rapid Test Kit
(Immunochromatography)

Product Name

25(OH)VD Rapid Test Kit (immunochromatography)

Intended Use

The 25(OH)Vitamin D assay is only intended as an invitro diagnostic kit, designed for the determination of 25(OH) Vitamin D in human serum/plasma/whole blood samples.

Principle

The 25(OH) Vitamin D assay kit is designed for the serological determination of the vitamin D concentration according to the principle of Immunochromatography in the human serum/plasma/whole blood samples. The test line (T) is marked with 25(OH)VD. There is a cushion containing anti-25 (OH) VD monoclonal antibody - latex marker at the bottom of the reagent strips. The sample mixing up 25 (OH) VD monoclonal antibody – marker while testing, move along the membrane to the T line. When the sample concentration 25 (OH) VD reaches 75 ± 10 nmol / L or higher, combination of vitamin D and marker will be blocked. Therefore, a sample of an adequate concentration does not make test line showing color. When the sample concentration 25 (OH) VD below 75 ± 10 nmol / L (30 ± 4ng /m L), the anti-25 (OH) VD monoclonal antibodies -marker will react with 25 (OH) VD in the position of T line and shows the color. The control line (C) is the other reaction line of another antigen / antibody reaction which will always appear in the detection, and will not rely on the existence of 25(OH) Vitamin D. C line can be used as an internal quality control reference index, appearance of C line indicating the correct detection operation and the reaction system is working properly.

Main components

1. Testing strip: each strip is consist of anti-25 (OH) VD monoclonal antibody, nitrocellulose membrane marked by goat anti-mouse IgG and cushion marked by 25(OH)VD.

2. Disposable pipette

3. Buffer: Buffer: Tris-base buffer saline solution, saved in sodium azide with a concentration of less than 0.01%

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board.

4. Instructions

Storage and Validity

Store at dry place with room temperature 2-30 ℃, avoid hot, sunshine and corrosive gases. No frozen, usually without refrigeration.

If stored in the required condition, it can stabilize the expiration date on the package identified (valid for 24 months)

Test strip should be kept in the sealed bag until use, Test immediately after opening, no further storage.

Sample Requirements

Remove serum and assay immediately after venous blood collection when using serum sample to avoid hemolysis. After the separation, samples can be stored at 22 ℃ for less than 8 hours, store at 2-8 ℃ for less than 48 hours, can be stored for 2 months at -20 ℃. Avoid repeated freeze-thaw cycles.

Collect blood from both sides of left hand ring finger when using fresh whole blood (without anticoagulants). Be sure to clean and disinfect before collect blood, and do not collect blood until the iodine or alcohol dried in the air.

Squeezing finger is not allowed during the blood collection. Massage your finger before blood collection to get sufficient blood. Drop the arms for 10-15s to get the tip of the finger congestion. Push the finger gently on both sides to one-third of the finger tip, so that the blood can spill over slowly. Detect immediately after collecting blood.

Hyperlipidemia and jaundice blood samples are not suggested to use.

Test Methods

1.materials required but not supplied

1.1timer

1.2container which may be contaminated

1.3 Disposable pipette tips or blood collection tubes

2. Test procedure

2.1Take off the outer packing, put the cassette onto the desk with the sample window up(Please test as soon as possible after taking out)

2.2 Using a pipette to drop one drop of specimen (11μl whole blood or 6μl serum/plasma) vertically into the circular groove of cassette with S.

2.3 Add 3 drops (about 100μl-120μl) specimen buffer into the circular groove of cassette with B. (Do not move the cassette while testing)

2.4 Observe the result immediately within 10-15 minutes.

Reference interval

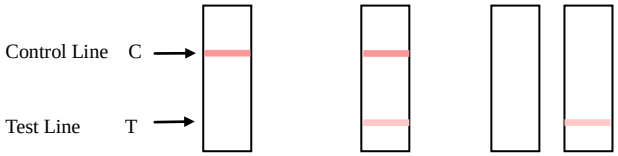
This product has been tested on people of three ages which are ≤15 years old、15～55 years old、≥55 years old. Statistical analysis is as follows: Concentration higher than 85nmol / L is negative, concentration lower than 65nmol / L is positive. Each laboratory should establish range of clinically normal and pathological values of its own.

Interpretation of results

Negative**:** Only one red band (C) appears in the detection zone, without the red band appears area (T).

Positive**:** Two red bands appear, one in the test area (T), the other in the control area(C).

Invalid**:** No red line appears or T line appears, indicating that the operator error or reagent failure.



Negative Positive Invalid

Attention: Lines in the test area can appear of different color depth. Within a specified observation time, regardless of the line color depth, even if only a very weak color should be judged as a positive result.

Limitations

The line color will change with the concentration of 25 (OH) VD.

Products performance indicators

1.Coincidence rate of negative reference products: 25 (OH) VD negative reference products cannot detect the positive results.

2.Coincidence rate of positive reference products: 25 (OH) VD positive reference products cannot detect the negative results.

3.Sensitivity: Sensitivity should be no higher than 65 nmol / L.

4.Inter variations: For the same 25 (OH) VD positive reference, the test results shall be all the same.

Attentions

1.The reagent only can be used for screening tests, cannot be used for other purposes.

2.Do not use reagents which have lost efficacy.

3.All specimens and reagents should be dealing with as contaminated waste by incineration or other ways after used.

4.After testing, abandoned test shall be discarded in the proper biological waste container.

5.Do not use repeated blood collector

6.The patient specimens may be false positive or false negative

7.We recommend purchase quality control materials from the third party manufacturers or companies.

8.Test environment temperature should be 15 ~ 25 ℃

9.Add the buffer liquid immediately after adding the blood specimens. Test result is invalid if the blood clotting.