# CDIA™ 25-OH-Vit-D Immunofluorescence Test Cassette (Serum)

*Cat. No.: DTSJYJ004*

*Pkg. Size: 25T*

## Intended Use

This kit is the quantitative detection of content of 25-hydroxyvitamin D (25-OH-Vit-D) in human serum samples.

## General Description

Vitamin D is a fat-soluble steroid derivative, and vitamin D is derived from sunlight for the skin. Skin synthesis of vitamin D is transported to the liver by binding to the vitamin D binding protein, while the absorbed vitamin D is transported to the liver by conjugation with chylomicrons and lipoproteins. Vitamin D deficiency is prevalent in the world, affecting 30% to 50% of people. 25-hydroxyvitamin D (25OHD) determination is the best indicators for measuring vitamin D nutritional status.This kit is the quantitative detection of content of 25-hydroxyvitamin D (25-OH-Vit-D) in human serum samples.

## Principle of the Test

Based on the principle of competitive method, the content of 25-OH-Vit-D in samples will be quantitatively detected by immunochromatography technology. The 25-OH-Vit-D in sample and 25 hydroxyvitamin-D-BSA protein compounds compete the binding site of the fluorescent marked rat- anti-human 25-OH-Vit-D antibody on the microspheres. After a particular wavelength excitation there will be fluorescence signal in the reaction zone, the strength of the signal is inversely proportional to the 25-OH-Vit-D content in the sample.

## Reagents And Materials Provided

1. Cassette device, 25T
2. Sample buffer
3. Data card
4. Kit insert

Note: The components in different batch kit are not interchangeable. Different batches of data cards and reagents can't be used.

## Sample Requirements

1.This kit is suitable for serum, and it is recommended to use fresh samples.

2.Samples are stored at 2 - 8 °C for 7 days, and at -20 ± 5 °C for 3 months. To avoid repeatedly freezing and thawing, the times for freezing and thawing should be no more than 3 times.



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3.Before testing, samples must be returned to room temperature. Frozen samples must be completely melted, reheated, mixed even before using.

4.Sample: bilirubin ≤ 66 mg/dL, fat milk ≤ 400 mg/dL, rheumatoid factor ≤ 150 IU/mL will not interfere with the test.

## Test Method

**Prepare before using:**

1. Turn on the analyzer, and preheat for 5 mins.
2. Place the test kit and sample at room temperature and use it when back to room temperature.
3. After unpacking the reagent kit, remove the data card into the analyzer and the analyzer will automatically read the data.
4. After the data message is read, unplug the data card and save it.
5. If the data card information is read correctly, the current batch number can be used for the standard curve data.

**Test Procedure：**

1. Remove the detection card from the aluminum foil bag.
2. Use the appropriate range of the liquid to absorb the samples of 80 μL to be added to the sample diluent, vortex oscillate and mix with 5-10 s sufficiently with each other.
3. Absorb mixed sample 80 μL, and add it to the sample hole, and avoid obvious bubbles when drawing and adding samples.
4. Insert the detection card into the detection slot and read the test result at 15 min.
5. Take out the testing card and process it according to the potentially hazardous wastes.

Note: Quality control should be carried out on a regular basis to ensure the effectiveness and accuracy of the test results.

## Reference Range

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By measuring the content of 25-OH-Vit-D in 200 samples, the 95% confidence interval of the reference value was calculated by the percentile method. The reference interval was:

25-OH-Vit-D > 30 ng / mL

The above reference value represents only the expected value of this law, for reference only. The levels of 25-OH-Vit-D are different due to the normal and reasonable differences caused by different regions and different individuals, and the usage of different methods for testing. some factors, such as ultraviolet radiation, seasonal changes, subspecies, feeding, etc., will affect the concentration of 25-OH-Vit-D in human, the lack of sub-clinical status of 25-OH-Vit-D in many countries is generally popular, especially in the winter. It is recommended that the laboratory should establish their own reference range.


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## Result Interpretation

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1.The test results of this reagent is for clinical reference only. The clinical diagnosis and treatment of patients should be combined with its symptoms, signs, history, other laboratory tests and treatment reactions and other considerations.

2.The clinician is in need of confirmation test if there is any doubt about the test result or if the test result is obviously abnormal.

3.Operation errors, sample factors, the environment, etc. may have an impact on the test results.

## Limitation

1. This reagent is only for in vitro diagnostics of human serum samples.

2. Operation must be in strict accordance with the operating procedures, careful operation to get the correct results, any changes of the operating procedures may affect the results.

3. Unreasonable sample collection, transport and treatment, the sample concentration of the measured substance is too low, etc. may lead to false negative results.

## Performance

1.Blank limit: ≤ 3 ng/mL

2.Linear range: The linear range of reagents is 3-70 ng/mL, and the linear correlation coefficient should not be less than 0.990 in this linear range.

3.Repeatability: Repeat the test with the quality control, the coefficient of variation (CV) of test results ≤ 15%.

4.Batch difference: Repeat the test with three batches of quality test kit, coefficient of variation (CV) of test results ≤ 15%.

5.Accuracy: Recovery rate (R) between 85% to 115%.

## Storage and Validity

Keep at 4-30 °C, valid for 12 months. Do not be frozen. Test card should be used within 30 min as soon as possible after opening the separate package seal.

Note: Please refer to the label for the date of production and the validity date.

## Note

1.This kit is for in vitro diagnostic purposes only.

2.Do not swallow the reagent or contact with the skin, eyes and mucous membranes, once the contact, the contaminated parts should be washed with water



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3. Detection of temperature is 15-30 °C, and humidity 40% to 60% is the best.

4. Once the test card is removed from the aluminum foil bag, the experiment should be carried out as soon as possible to avoid the time which card placed in the air too long, leading to moisture.

5. All samples of the patient should be treated as a potential source of infection.

6. If the reagent has exceeded the validity period, it can no longer be used.



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