

25-hydroxyvitamin D (25-OH-D) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography)

Instruction For Use



In Vitro Diagnosis
For Professional Use

[Product Name]

25-hydroxyvitamin D (25-OH-D) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography)

[Package Specification]

25 tests/kit

[Intended Use]

This kit is used for the detection of 25-hydroxyvitamin D (25-OH-D) levels in human whole blood, serum and plasma samples in vitro quantitatively. For Professional Use Only.

[Test Principle]

The 25-OH-D Test Cassette is a fluorescent lateral flow immunoassay, which adopts a competitive assay method to quantitatively detect the concentration of 25-OH-D in human whole blood, serum, plasma. The test consists of: 1) a probe conjugate pad containing anti- 25-OH-D antibody conjugated with fluorescent microspheres (antibody probe conjugate) and a control antibody (goat anti-chicken IgY) conjugated with fluorescence microspheres, 2) a nitrocellulose membrane with immobilized proteins in the test area (T line) and a control area (C line). The T line is pre-coated with 25-OH-D antigen, and the C line is pre-coated with a control line antibody (chicken IgY). The specimen to be tested is added to the sampling hole of the test card, as the liquid flows, specimen to be tested first passes through the sample pad and forms a fluorescent complex with the probe pad fixed with quantum dot-labeled antibodies. The complex passes through the detection line and quality control lines, specifically immunobind with the antibodies in the detection line and quality control line respectively, and are captured by the coating antibodies on the nitrocellulose membrane to present fluorescent bands.

Intensity of the fluorescence signal reflects the amount of captured 25-OH-D. The higher the concentration of 25-OH-D in the sample, the more accumulated complexes on the detection line, the higher signal intensity will be tested out. Use a fluorescence immunoassay analyzer to analyze the photoelectric values of the quality control line and detection line, then the analyzer calculates the concentration of 25-OH-D based on the calibration curve that has been preset inside the analyzer and displays the result in ng/mL.

[Main Material]

Main Material as below:

- 25 Test cassettes
- 25 Empty centrifuge tubes
- 1 Bottle of dilution
- 1 ID Card
- 1 User Manual

Material Required but not Provided:

1. Timer, thermometer, hygrometer;

Note: Components of different batches of reagent kits cannot be used interchangeably to avoid incorrect results.

[Storage Conditions and Validity Period]

1. The test kit should be stored at 2~30°C, protected from light, and has a shelf life of 18 months.
2. The test cassette should be used within 1 hour after opening at a temperature of 2°C to 30°C and a humidity of 35% to 65%.

[Applicable Analyzer]

Dry fluorescence immunoassay analyzer GKYG-500 produced by Dezhou Guoke Medical Technology Co.,Ltd.

[Specimen Requirement]

1. Use conventional methods to collect, separate and obtain whole blood, serum and plasma, and try to avoid hemolysis during processing. Hemolyzed specimens cannot be used. All specimens should be treated as infectious agents.
2. Plasma specimens are allowed to use EDTA, heparin and sodium citrate anticoagulants.
3. After collection of clinical whole blood, serum, plasma specimens, the test should be completed within 24 hours at room temperature (15°C~30°C); serum and plasma samples can be stored for 6 months below -20°C and 7 days between 2°C and 8°C.
4. If the sample contains particulate matter, it will affect the test results. Samples containing visible particles should be centrifuged and the supernatant should be taken for experiments.
5. Do not test samples from patients with hemolysis, lipemia and jaundice.
6. Avoid using microbiologically contaminated samples.
7. Frozen samples should be completely thawed, rewarmed and mixed well before use. Do not freeze or thaw repeatedly, it is recommended that the sample be frozen or thawed no more than once.

[Test Procedure]

1. When stored at low temperature, the test kit and diluent should be restored to 18~26°C before use.
 2. Turn on the analyzer according to the analyzer instruction manual.
 3. Take out the ID card from the kit and read the ID card information at the card reading position of the fluorescence immunoassay analyzer.
 4. Tear open the outer packaging, take out the test cassette, and place it flat on the operating table. The removed test cassette should be used within 1 hour.
 5. Take 80 µl of the dilution into an empty centrifuge tube and set aside.
 6. Accurately pipette 20µl of the sample into a tube of sample diluent, and then repeatedly aspirate and dispense (or shake) it 10 times to mix thoroughly, ready for later use. Add 100µl of diluted sample to the sample well of the test card and start the clock.
 7. Immediately insert the test cassette into the fluorescence immunoassay quantitative analyzer at 15 minutes of reaction, click the "Detect" button, the test results will automatically be displayed on the instrument screen, and the results can be saved and printed.
 8. Used test cassettes should be treated as potentially biohazardous items.
 9. Quality control:
 - 1) C line is used as an indicator of the effectiveness of the test cassette, C line should appear in any cases.
 - 2) The company's internal quality control products or other approved and applicable quality control products can be used to conduct quality control on the product. The test results should be within the specified quality control range.
- Note:** Test should be completed at a temperature of 18°C to 26°C and a humidity of 35% to 65%.

[Positive Judgment Value or Reference Interval]

Vitamin D deficiency: ≤20ng/mL;

Vitamin D insufficiency: 21ng/mL-29ng/mL;

Optimal levels of vitamin D ≥ 30 ng/mL Each laboratory should experimentally determine the applicability of the reference range and establish its own laboratory reference range if necessary.

The reference value is verified with reference to similar products on the market. Due to racial and regional differences, each laboratory can establish its own reference interval based on actual conditions.

[Interpretation of Test Results]

1. 25 Hydroxyvitamin D levels below reference values suggest vitamin D deficiency.
2. When the applicable instrument indicates an invalid result, this is an indication of incorrect operation or that the kit has deteriorated and become damaged, in which case the instructions should be read again carefully and the test repeated with a new kit. If the problem persists, stop using the batch

immediately and contact your local supplier.

3. When diagnosing a patient, make a comprehensive judgement in conjunction with other test results or clinical symptoms.

[Limitations of Detection Method]

This kit is a fluorescence immunochromatography diagnostic kit and has inherent methodological limitations:

1. The test results can only be used as an auxiliary for doctors or other diagnoses and need to be combined with other clinical and laboratory data. If the test results are inconsistent with the clinical assessment, further examination is required.
2. This kit is for human serum, plasma or whole blood only.
3. High concentrations of triglycerides, cholesterol, bilirubin and high concentrations of haemoglobin due to haemolysis can interfere with the chromatographic process of the sample and the couplings on the nitrocellulose membrane, resulting in potentially false test results. Therefore, samples with severe lipaemia, severe haemolysis or severe jaundice should not be used in the test.
4. Bilirubin $\leq 0.5\text{mg/mL}$, triglycerides $\leq 10\text{mg/mL}$, hemoglobin $\leq 5\text{mg/mL}$, would affect the test result, and the deviations are within $\pm 10\%$.
5. The results of the kit are for clinical reference only and cannot be used alone as a basis for confirming or excluding a case. For diagnostic purposes, the results of this test should be used in conjunction with the clinical examination, medical history and other test results.

[Product Performance Indicator]

1. Appearance inspection: The product and outer packaging should be clean and smooth, with clear markings, complete components, and strong material attachment.
2. Migration speed: The liquid migration speed should not be less than 10mm/minute.
3. Linear range:
In the range of 5ng/mL - 70ng/mL, the Correlation Coefficient(R) value should be ≥ 0.990 .
4. Accuracy
Use company's internal control accuracy reference products (C1, C2) to test, and the test results should be within the following range:
1) Using company's internal control accuracy reference product C1: 10ng/mL for testing, the analyzer's measurement range is 10ng/mL $\pm 15\%$ at 15 minutes;
2) Using company's internal control accuracy reference product C2: 30ng/mL for detection, the analyzer's measurement range is 30ng/mL $\pm 15\%$ at 15 minutes;
5. Intra-Lot precision
Use the company's internal control precision reference materials (C9: 10ng/mL, C10: 30ng/mL) for 10 parallel tests each, and measure with the analyzer at 15 minutes. The concentration value variation coefficient CV $\leq 15\%$.
6. Inter-Lot precision
For the three batches of kits, the company's internal control precision reference materials (C9: 10ng/mL, C10: 30ng/mL) were tested 10 times in parallel. The analyzer measured the concentration value at 15 minutes, and the concentration value variation coefficient CV $\leq 15\%$.
7. Detection limit
Use the company's internal control detection limit reference product L1 to test, and measure with the analyzer at 15 minutes. The result should be $\leq 4\text{ng/mL}$.
8. Specificity
Using the company's internal control specific reference materials (C3, C4, C5, C6, C7, C8) to detect, the measured values of the analyzer should be less than 4ng/mL at 15 minutes.

[Precautions]

1. This kit is only for in vitro diagnosis, one-time use, please do not re-use.
2. The test kit should be treated as contain infectious material.
3. Please check the integrity and expiration date of the kit packaging before use.
4. Please read the instructions for use of this reagent and instrument carefully before any operation.
5. Please strictly follow the instructions. After the test starts, it cannot be stopped in halfway. If it is stopped halfway, the test cannot be resumed. If a

retest is needed, use new reagents and retested.

6. Each batch of reagents has corresponding parameters in the supporting analyzer, and the manufacturer regularly updates the parameters in the analyzer. If the new batch of product reagents is not recognized by the analyzer, please contact the manufacturer in time to update the parameters.
7. The test cassette shall not be used after more than 1 hour after opening.
8. Reagents with different batch numbers cannot be mixed, and ID cards and test cassettes must not be used with mixed batch numbers.
9. The experimental environment should be avoided from being too high. Test cassettes stored at low temperature need to be returned to room temperature before opening to avoid moisture absorption.

Code:GKPD052-1 Effective date: May,31,2024

[Index of Symbols]

	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
	Temperature scope within which the product is reserved		Batch number
	Catalog #		Tests / box
	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		



Manufacturer:

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