

Human Chorionic Gonadotropin β (β -HCG) Quantitative Test Cassette

(Quantum Dot Fluorescence Immunochromatography)

Instruction For Use



In Vitro Diagnosis
For Professional Use

【Product Name】

Human Chorionic Gonadotropin β (β -HCG) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography)

【Package Specification】

25 tests/kit

【Intended Use】

This kit is used for the detection of Human Chorionic Gonadotropin β (β -HCG) levels in human whole blood, serum and plasma samples in vitro quantitatively.

For Professional Use Only.

【Test Principle】

The β -HCG test kit is fluorescence lateral flow immunoassay, which adopts a double antibody sandwich method to quantitatively detect the concentration of β -HCG in human whole blood, serum and plasma. The test consists of: 1) a conjugate pad containing anti-HCG monoclonal 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 antibodies in the test area (T line) and a control line (C line). The T line is pre-coated with another anti-HCG antibody, and the C line is pre-coated with a control line antibody (chicken IgY Ab). 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 β -HCG. The higher the concentration of β -HCG 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 β -HCG based on the calibration curve that has been preset inside the analyzer and displays the result in mIU/mL.

【Main Material】

Main Material as below:

- 25 Test cassettes
- 25 Deliver pipettes
- 25 Diluent bottles
- 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 24 months.
2. The test cassette should be used within 1 hour after opening at a temperature of 20°C to 25°C and a humidity of 35% to 65%.

【Applicable Analyzer】

Fluorescent immunoassay analyzer with Excitation wavelength of 365nm and Emission wavelength of 610nm.

【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. whole blood, serum and plasma specimens should be stored at 18 to 28°C for no more than 1 day. If the specimen is free of bacterial contamination, it should be stored at 2 to 8°C for no more than 3 days, and at -20°C for no more than 1 month, repeated freezing and thawing should not occur more than 3 times. Frozen specimens should be thoroughly mixed after thawing.
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. The specimen must be restored to 20~25°C before testing. Frozen and preserved specimens must be completely thawed, rewarmed, and mixed evenly before use.

【Test Procedure】

1. When stored at low temperature, the test kit and diluent should be restored to 20~25°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. Collect 50µl of sample (whole blood, serum and plasma), add to the sample diluent (mix thoroughly for 30 sec with vortex mixer), collect 80µl of a sample mixture and slowly add it vertically to the sampling hole of the test cassette, and start timing.
6. 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.
7. Used test cassettes should be treated as potentially biohazardous items.
8. 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 20°C to 25°C and a humidity of 35% to 65%.

【Positive Judgment Value or Reference Interval】

Normal Range: <10mIU/mL.

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. If the whole blood, serum and plasma sample is turbid, it will affect the flow rate of the sample, resulting in prolonged detection time or failure to detect, resulting in possible erroneous detection results. Please centrifuge and discard the sediment before use.
2. The accuracy of the sample amount will directly affect the accuracy of the test results.
3. Please check the integrity and expiration date of the kit package before use, then open the package. Low-temperature storage should be restored to 20~25°C before opening the package for use. Direct use at low temperatures will affect the test results.

【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. 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 $\pm 10\%$.
3. The HOOK effect does not appear when $\beta\text{-HCG}$ concentration is $\leq 80000\text{mIU/mL}$.
4. If the sample test result shows more than 50000mIU/mL, it is recommended to dilute the sample with saline (the maximum dilution should not exceed 1:5), and the concentration value of the test obtained after the dilution should be calculated in accordance to the dilution ratio.

【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 5mIU/mL-50000mIU/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: 500mIU/mL for testing, the analyzer's measurement range is 500mIU/mL \pm 15% at 15 minutes;

2) Using company's internal control accuracy reference product C2: 5000mIU/mL for detection, the analyzer's measurement range is 5000mIU/mL \pm 15% at 15 minutes;

5. Intra-Lot precision

Use the company's internal control precision reference materials (C9: 500mIU/mL, C10: 5000mIU/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: 500mIU/mL, C10: 5000mIU/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 5mIU/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 5mIU/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.

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[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:

Dezhou Guoke Medical Technology Co., Ltd

Add: 28-31 axis,1 and 2 span, No.2 workshop, (Zhongyuan Science and Technology Innovation Park) No. 6596 Dongfanghong East Road, Yuanqiao Town, Economic and Technological Development Zone, Dezhou City, Shandong Province.
E-mail: office@guoke-medical.com



European Authorized Representative:

Riomavix S.L.

Add.: Calle de Almansa 55,1D, Madrid 28039 Spain
E-mail: leis@riomavix.com