# Progesterone (Prog) Quantitative Test Cassette
## (Quantum Dot Fluorescence Immunochromatography)
## Instruction For Use

CE IVD REF

**In Vitro Diagnosis**
**For Professional Use**

**【Product Name】**

**Progesterone (Prog) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography)**

**【Package Specification】**

25 tests/kit

**【Intended Use】**

This kit is used for the detection of Progesterone (Prog) levels in human whole blood, serum and plasma samples in vitro quantitatively.
For Professional Use Only.

**【Test Principle】**

The Progesterone Test Cassette is a fluorescence lateral flow immunoassay, which adopts a competitive method to quantitatively detect the concentration of Progesterone in human whole blood, serum and plasma. The test consists of: 1) a conjugate pad containing anti-Progesterone 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 proteins in the test area (T line) and a control line (C line). The T line is pre-coated with another Progesterone antigen, 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 Prog. The higher the concentration of Prog 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 Prog 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 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 -2°C for no more than 3 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 10~30℃ and gently turn to mix evenly before testing. Do not use water bath heating to thaw frozen samples. 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 18~26℃ 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 0.15 ml of the dilution into an empty centrifuge tube and set aside.
6. Accurately pipette 100μl of the sample into one sample diluent tube, oscillate to mix thoroughly, and keep it ready for 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】**

Reference range of progesterone levels in normal human blood:
Male: 0.1 -2.0ng/mL;
Female: 0.2-1.6ng/mL in follicular phase, 2.0-22.5ng/mL in luteal phase, 0.1-1.0ng/mL in menopause;
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 test result shows that the progesterone (Pro) level is within the reference range, it is considered normal; if the test result shows that the progesterone (Pro) level is in the critical region, it should be re-measured for confirmation; if it is obviously out of the reference range or still out of the reference range after the confirmation test, it is considered to be a high level of progesterone (Pro), which suggests symptoms of kidney damage.

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, use a combination of 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 whole blood, serum and plasma testing only.
3. Severe coeliac blood samples may clog the pore of the nitrocellulose membrane, resulting in elevated results due to background enhancement, and should not be measured by this method. High concentrations of haemoglobin caused by haemolysis may affect the chromatographic process and cause false results.
4. Bilirubin ≤0.5mg/ml, triglycerides ≤10mg/ml, hemoglobin ≤5mg/ml would affect the test result, and the deviations are within ±10%.
5. If the sample test result shows more than 60ng/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 0.2ng/ml-50ng/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: 5ng/ml for testing, the analyzer's measurement range is 5ng/ml±15% at 15 minutes;
2) Using company's internal control accuracy reference product C2: 10ng/ml for detection, the analyzer's measurement range is 10ng/ml±15% at 15 minutes;
5. Intra-Lot precision
Use the company's internal control precision reference materials (C9: 5ng/ml, C10: 10ng/ml) for 10 parallel tests each, and measure with the analyzer at 15 minutes. The concentration value variation coefficient CV ≤ 15%.
6. Inter-Lot precision
For the three batches of kits, the company's internal control precision reference materials (C9: 5ng/ml, C10: 10ng/ml) were tested 10 times in parallel. The analyzer measured the concentration value at 15 minutes, and the concentration value variation coefficient CV ≤ 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 ≤0.1ng/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 0.1ng/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.
10. With regard to the warning on components of animal origin, the components of the kit contain serum proteins of bovine origin, which are collected from quarantined animals in non-infected areas and are negative for sterility, mycoplasma and viruses, but as of now, no test can ensure absolute safety, and the components should be treated as a potential source of infection.

**Code:GKPD063-1 Effective date: May,31,2024**

**【Index of Symbols】**

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|---|---|---|---|
| IVD | 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 |
| 2℃-30℃ | Temperature scope within which the product is reserved | LOT | Batch number |
| REF | Catalog # | Σ | Tests / box |
| EU REP | European union authorized representative | | Keep dry |
| | Keep away from sunlight | | Don't use the product when the package is damaged |
| | Biological risks | | |
| CE | The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC | | |

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