PROG Rapid Quantitative Test

Catalog No.: BT2203

INTENDED USE

The Biotime PROG (Progesterone) Rapid Quantitative Test is intended to quantify the concentration of PROG in human serum on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of ovulation, the progesterone replacement therapy and hormone.
-Fluorescence immunoassay
-Ovulation, the progesterone replacement therapy and hormone
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

PROG Rapid Quantitative Test is used to detect the concentration of PROG in human serum.
The Progesterone (PROG) is a kind of steroid containing 21 carbons that is an intermediate metabolite production with the synthesis of steroid. PROG in blood is almost manufactured by the corpus luteum and placenta in female, while it is mainly secreted by adrenal cortex in male. Furthermore, about 97% to 98% of PROG can combine with Albumin and corticosteroid-binding globulin, CBG) of reversibility. It is metabolized in the live, decomposed into pregnanediol, water soluble sulfateand glucose derivative, and then excreted with urine. PROG is regarded as a significant steroid not only playing an important faction to adjust the stage of menses, but also maintaining the encyesis. At the later stage of menstruation, PROG brings about the growing of the gland in uterine mucosa, congestion of uterus and an increase of thickness of endometrium to prepare for implantation of the fertilized egg. After implantation of the fertilized egg, PROG makes it produce a placenta, reduces the exciting of the pregnant uterus and forbids its action to make the fetus grown safely. The concentration of PROG will rise up quickly in serum after ovulation, so that it is regarded as a reliable label of natural ovulation or ovulation induction. Thus it is a reliable method to forecast the possible abortion and abnormal gestation. Furthermore, it is applied to ensure the ovulation, to monitor the progesterone replacement therapy, to evaluate the first trimester and to judge the condition of the hormone[1].
Therefore it is an absolutely necessary method to study the Ovarian physiological and pathophysiology.

PRINCIPLE

This reagent is based on fluorescent lateral flow immunoassay competition method.
While the sample and the buffer are mixed, The PROG in specimen and mouse anti-PROG monoclonal antibody labeled with fluorescent microsphere(contain Europium) form a reaction complex. During lateral flow, Free labled antibodies moves along with the nitrocellulose membrane to a detection line (T-line: coated with PROG antigen). Free labled antibodies are captured and gives fluorescent signal upon stimulation. Thus the fluorescent signals are negatively correlated with the concentrations of PROG in human serum.
The fluorescent signal will be quantified and calculated according to the calibration curve (provided with the reagents) to represent concentration of PROG in human serum.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for one-time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. It may cause damages to the instrument.

MATERIAL

Material Provided
1. Test cartridge 25 tests/kit
2. Detection buffer 25 tubes/kit
3. SD Card 1 piece/kit
4. Instructions for use 1 copy/kit

Material Required But Not Provided
1. Biotime FIA Analyzer
2. Transfer Pipette Set (range 10~100μL size)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-8℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge shall be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with serum.
2. The specimen collection container should be pro-coagulant tube for serum.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected in time, it can be stored in refrigerator at 2-8℃ for no more than 7 days，or at -20℃ for no more than 6 months. Samples must be recovered to the room temperature before tests.
4. Separate the serum or plasma from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to the operation manual of Biotime FIA Analyzers for details.
The test should be operated at room temperature(~25℃).
Step 1: Preparation
Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.
Step 2: Sampling
Take 40uL of serum with a transfer pipette and add it into the buffer tube.
Step 3: Mixing
Mix well the specimen with buffer by tapping or inverting the tube.
Step 4: Loading
Take 80μL of sample mixture and load it into the well of the test cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.
Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 10 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Note: Individual reference range is suggested to be established for each laboratory.
Normal reference interval(ng/mL):
Male:NG-0.97
Female:Follicular phase(NG-7.00), Ovulatory period(0.60-4.50), Luteal phase(2.00-25.00), Mneopause(NG-1.60)
First trimester:8.6-49.36 Second trimester:12.5-＞80 Third trimester:59.62-＞80

LIMITATIONS OF PROCEDURE

1. The test sample should be serum.
2. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results.
3. However, the test result must be carefully evaluated when patients are known to have these antibodies[2-3].
4. Other factors also can induce the false results, include the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
PROG control materials with two different concentrations were tested by every batch of Test Cartridges, and the deviations were within ±15%.
Assay Range: 0.30-80.00ng/mL
The Lowest Detection Limit: 0.30ng/mL
Linearity
A serial concentrations of PROG reference materials at 3.00-80.00ng/mL were tested, and the correlation coefficient (R) is ≥ 0.9900.
Precision
Intra-lot Precision
Intra-lot precision was determined by testing of PROG reference materials using 10 test cartridges from the same batch. The C.V. is ≤ 15%.
Inter-lot Precision
Inter-lot precision was determined by testing of PROG reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each batch).The C.V. is ≤ 20%.
Specificity
The concentration of PROG is not greater than 0.3ng/mL when the concentration of estradiol is 500ng/mL.
The concentration of PROG is not greater than 0.3ng/mL when the concentration of testosterone is 500ng/mL.
The concentration of PROG is not greater than 0.3ng/mL when the concentration of cortisol is 500ng/mL.
The concentration of PROG is not greater than 0.3ng/mL when the concentration of aldosterone is 500ng/mL.
The concentration of PROG is not greater than 0.3ng/mL when the concentration of estriol is 100ng/mL.
The concentration of PROG is not greater than 0.3ng/mL when the concentration of 17-β estradiol is 100ng/mL.
The concentration of PROG is not greater than 0.3ng/mL when the concentration of oestrone is 100ng/mL.
The concentration of PROG is not greater than 0.3ng/mL when the concentration of 17-α hydroxyl progesterone is 100ng/mL.

SMYBOLS

Symbol	Description	Symbol	Description
	Catalogue number		In vitro diagnostic medical device
	Batch code		Consult instructions for use
	Date of manufacture		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer		Store at 2-8℃
	Do not re-use		Store at 2-30℃
	CE mark		Authorized representative in the European

BIBLIOGRAPHY OF SUGGESTED READING

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3. Levinson SS. The Nature of Heterophilic Antibodies and the Role in Immunoassay Interference.[J]. J of Clin Immunoassay, 1992, 15:108-114.

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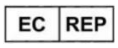

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