PROG Rapid Test Kit

Instructions for use

IVD For in vitro diagnostic use only.

REF A02042004

Σ 25 Tests

【Product Name】

PROG Rapid Test Kit

【Intended Use】

The PROG Rapid Test Kit along with Anbio FIA Meter is a fluorescence immunoassay for quantitative measurement of Progesterone (PROG) in human serum or plasma. The test is used as an aid to track ovulation, monitor the effect of progesterone therapies and in early pregnancy to help diagnose an ectopic or failing pregnancy.

For professional use only.

【Summary】

Progesterone is a female hormone produced by the ovary. It is important for the regulation of ovulation and menstruation of human.During the follicular phase of the menstrual cycle, progesterone levels remain low. Following the LH surge and ovulation, luteal cells in the ruptured follicle produce progesterone in response to LH thus the progesterone level rises rapidly at day 5-7 following ovulation. During the luteal phase, progesterone transforms the estrogen-primed endometrium from a proliferative to a secretory state. If pregnancy does not occur, progesterone levels decrease during the last four days of the cycle.

If the conception occurs, during the first trimester the ovaries will produce progesterone maintaining at mid-luteal level to help build and maintain the lining of the uterus to allow a fertilized egg to implant until the placenta takes over the function around the 9-10th week of pregnancy.

【Test Principle】

The Anbio PROG Rapid Test Kit is based on fluorescence immunoassay technology. The Anbio PROG Rapid Test Kit uses a competitive immuno detection method. When sample is added to the sample well of the Test Device, the fluorescence-labeled detector PROG antibody binds to PROG antigen in the specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the antigen-antibody complexes can't be captured to PROG antigen that has been immobilized on test strip, but the rest of fluorescence-labeled antibody is captured. Thus the more antigen in the specimen, the less fluorescence-labeled antibody is accumulated on test strip. Signal intensity of detector antibody reflects the amount of PROG captured and Anbio FIA Meter shows PROG concentration in the specimen.

【Main Components】

The following components are included in the PROG Rapid Test Kit:

Supplied Materials:

Component	Main Ingredients
Test Cartridge	1) T line: PROG antigen (coated) 2) C line: Goat anti-rabbit IgG polyclonal antibody 3) Binding pad: Fluorescent microsphere-labeled mouse anti-PROG monoclonal antibody (labeled) and fluorescent microsphere-labeled rabbit IgG polyclonal antibody
IC Card	/
Sample Diluent	10mmol/L PBS

Materials Required but not Provided:

1. Transfer Pipette Set
2. Specimen Collection Containers
3. Centrifuge (for Plasma/Serum only)
4. Timer
5. Anbio FIA Meter (model number: AF-100, AF-100s, AF-1200, AF-100C)

【Storage Conditions and Shelf Life】

Component	Storage- Temperature limitation	Stability
Test Cartridge	30°C / 2°C	The shelf life is up to 24 months. Please refer to use-by date on the label. Test Cartridge should be used within 1 hour after opening the pack.
IC Card		/
Sample Diluent		The diluent is stable up to 24 months. Please refer to use-by date on the label.

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【Warnings and Precautions】

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with IC Card # that is inserted onto the equipment.
5. The Anbio PROG Rapid Test Kit is only operational in the Anbio FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector diluent tubes for different specimens.
9. The specimens, used Test Cartridges, pipette tips and detector diluent tubes should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

【Specimen Collection and Preparation】

The test can be performed with serum or plasma.The plasma sample is recommended to use EDTA, heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.

For Serum and Plasma:

1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

【Test Procedure】

Refer to Anbio FIA Meter Operation Manual (attached to Anbio FIA Meter) for the complete instructions on use of the Test. The test should be operated in room temperature .

Step1:Preparation

Check/ Swipe the IC Card information to the equipment.

Make sure the sample diluent is at the bottom of the tube by tapping or flicking before using.

Step2:Sampling

Draw 50 μL of serum/plasma with a transfer pipette and add it to the diluent tube.

Step3: Mixing

Close the lid of diluent tube and mix the specimen by shaking or tapping 6-8 times, until the specimen completely mixed. Let it stand 1 minute.

Step4: Loading

Take 50μL of sample mixture with a transfer pipette and load it into the sample well of the Test Cartridge.

Step5:Testing

Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click "Timing Test". 15 minutes later, the result will show in the display and print out when click "Print".

Quick test: Put the Test Cartridge on the operation platform.15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click "Quick Test". The result will show in the display and print out when click "Print".

【Limitations of Procedure】

1. This test has been developed for testing human serum and plasma specimen.
2. The results of Anbio PROG Rapid Test Kit should be evaluated with all clinical and laboratory data available. If PROG test results do not agree with the clinical evaluation, additional tests should be performed.
3. Incorrect results can be caused by interference from some similar substance in the sample.
4. Other factors may interfere with Anbio PROG Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in the specimens.

【Quality Control】

Internal procedural controls are included in the test. When testing, the quality control line (C line) will show a certain luminescence intensity, which is an internal procedural control. It confirms that a sufficient volume of samples has been added and that the correct procedure has been performed.

【Interpretation of Results】

The Anbio FIA Meter calculate the test result automatically and displays PROG concentration of the test sample in terms of ng/mL.

1. **Conversion Factors:**
   nmol/L x 0.314 = ng/mL (μg/L)
   ng/mL x 3.18 = nmol/L

2. The Reference Value

Gender	Phase	Reference value(ng/mL)
Male	/	<0.5-1.6
Female	Follicular Phase	< 0.5-2.0
	Ovulatory Phase	< 0.5-12
	Luteal Phase	1.8-29.2
	Postmenopausal	< 0.5
	1st trimester of Pregnancy	10.4-52.8
	2nd trimester of Pregnancy	21.8-58

Note: Individual reference range is suggested to be established for each laboratory.

【Performance Characteristics】

Limits and Range

Limit of Detection:0.5ng/mL ;
Limit of Quantitation:1.0ng/mL;
Measuring range: 1~60ng/mL;

Precision

Precision was determined with Anbio test kits, samples, and controls according to the CLSI (clinical and Laboratory Standards Institute) protocol (EP05- A3):

(1) 3 batches of test kits, repeated 10 times per batch (n=30)

ng/mL	Intra-batch						Inter-batch	
	Batch 1		Batch 2		Batch 3			
	SD	CV	SD	CV	SD	CV	SD	CV
4.96	0.421	8.35%	0.314	6.38%	0.340	6.91%	0.353	7.12%
24.69	1.948	7.94%	1.808	7.26%	1.823	7.41%	1.803	7.30%

(2) 3 laboratories with duplicate testing 5 times a day for 5 days (n = 75).

ng/mL	Repeatability		Intra laboratory precision		Inter laboratory precision	
	SD	CV	SD	CV	SD	CV
5.03	0.367	7.30%	0.367	7.30%	0.371	7.38%
24.87	1.645	6.61%	1.645	6.61%	1.669	6.71%

Limitations-Interference

Detection of the effects of the following endogenous substances on assay performance. Interfering substances detected in the listed concentration range had no effect on the results.

Compound	Concentration
Bilirubin	350μmol/L
Triglycerides	40mmol/L
Hemoglobin	2g/L
RF	1500IU/mL
HAMA	1000ng/mL
Antinuclear antibody	1:640

Limitations-Cross-Reactivity

The following substances do not interfere with the PROG test results at the indicated concentrations

Cross material	Concentration(ng/mL)
11-Deoxycorticosterone	500
Pregnenolone	14000
Cortisol	18000
Corticosterone	180
17α-Hydroxyprogesterone	2000
17β-Estradiol	400
estriol	10
Aldosterone	1000
Danazol	80000
11-Deoxycortisol	4000
Testosterone	1800
prednisolone	200

【Bibliography of Suggested Reading】

1.Qi Lu, Yuhong Li, Hong Shi, Xiao Lang, Yudong Wang. The value of ratio of hCG, progesterone in local blood of pregnancy location versus venous blood in the diagnosis of ectopic pregnancy. Int J Clin Exp Med, 2015 Jun 15; 8(6): 9477-9483.
2.Bernd R. Gardill, Michael R. Vogl, et al. Corticosteroid-Binding Globulin: Structure-Function Implications from Species Differences. PLoS ONE,2012, 7 (12): e52759.

【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
	Do not use if package is damaged and consult instructions for use		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
30°C 2°C	Temperature limit	LOT	Batch code
	Use-by date		Keep dry
	Keep away from sunlight	REF	Catalog number
	Date of manufacture	Σ	Contains sufficient for <n> tests

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