Progesterone（Prog）Rapid Quantitative Test (Fluorescence Immunoassay)
User manual

【Product name】
Progesterone（Prog）Rapid Quantitative Test (Fluorescence Immunoassay)

【Package specification】
25 Tests/kit、40 Tests/kit

【Intended use】
This kit is used for quantitative determination of progesterone in human whole blood, plasma and serum.
Progesterone is secreted by the ovarian corpus luteum in the early stage of pregnancy. It has a significant morphological effect on the endometrium stimulated by estrogen in vivo, which is necessary to maintain pregnancy. The main function is to maintain pregnancy, which is secreted by the placenta in the middle and third trimester of pregnancy. Low progesterone also indicates the deficiency of luteal function. Progesterone can maintain the growth of endometrium, which is conducive to the implantation and growth of fertilized eggs. Otherwise, it will delay the development of endometrium, fail to produce normal secretory response, and it is difficult to support the planting of fertilized eggs, resulting in infertility, or although it can be temporarily implanted, it cannot maintain its development and growth, and eventually lead to abortion. Repeated occurrence will lead to habitual abortion. Therefore, the detection of progesterone can be used to determine ovulation and luteal phase defects. In addition, the detection of progesterone can also monitor progesterone treatment and evaluate early pregnancy.

【Test principle】
The kit adopts the principle of competitive method. Take the sample to be tested, add it into the sample diluent and mix it evenly. Add the mixed sample into the sample adding hole. Prog in the sample combines with the fluorescent labeled antibody on the binding pad to form a complex. Under the action of chromatography, the complex moves forward along the nitrocellulose membrane, and the fluorescent labeled antibody that does not bind to the test line is captured by Prog-BSA coated on the nitrocellulose membrane detection line. The more Prog in the sample, the fewer complexes gathered on the detection line, and the signal of fluorescent antibody is inversely proportional to the number of objects to be tested in the sample. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25/40	It is composed of fluorescent pad (coated with fluorescent labeled Prog monoclonal antibody and fluorescent labeled biotin), nitrocellulose membrane (coated with Prog-BSA and GSA), absorbent paper and backing.
Sample diluent	25/40	Phosphate buffer
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】
The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.
The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable instruments】
Mod:NIR-1000 Dry Fluoroimmunoassay Analyser produced by WWHS Biotech.Inc.

【Sample requirements】
1. Plasma, serum and whole blood can be used as samples. The whole blood should be collected in a tube containing heparin, citrate or EDTA as the anticoagulant. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored at 2℃~8℃ for 24 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃for 30 days.
4. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Test procedure】
1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyser and correctly select the corresponding sample type on the instrument.
3. Take out the ID card, make sure that the batch number of the ID card is consistent with that of the test card, and insert the ID card into the ID card port of the instrument.
4. Take out the test card from the aluminum foil bag and use it within 15 minutes.
5. Place the test card on a clean horizontal table and mark it horizontally.
6. Mix 100 μL of sample with 200μL of sample diluent. Apply 100 μL of diluted samples to the well

of the test card.

7. At 15 minutes after addition of samples, insert the test card into NIR-1000 dry fluoroimmunoassay analyser and click the “Instant test” button to read the results.

【Reference interval】

Gender	Phase	2.5^{th} percentile （ng/mL）	97.5^{th} percentile （ng/mL）
Male	/	0	1.5
Female	Follicular phase	0	1.9
	Ovulatory phase	0	12.0
	Luteal phase	1.7	28.7
	Menopause	0	1.4
	Pregnancy（＜12weeks）	11.0	53.0
	Pregnancy（12-24weeks）	21.5	60.0

It is strongly recommended that each laboratory should determine its own normal and abnormal values based on population.

【Interpretation of results】

1. This reagent is only used for auxiliary detection. If the test results are abnormal, it should be reviewed in time and judged in combination with clinical symptoms.
2. For samples with Prog concentration lower than 1.40ng/mL and higher than 60.00ng/mL, the detection results are reported as "< 1.40 ng/mL " and ">60.00 ng/mL ", respectively.

【Limitations of methods】

1. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
2. The content of triglyceride in the sample shall not exceed 15mg/ml, the content of hemoglobin shall not exceed 5mg/ml, and the content of bilirubin shall not exceed 0.5mg/ml, and the relative deviation of the test results shall not exceed ±15%。
3. When the concentration of Prog in the sample is less than 600 ng/mL, there is no hook effect.
4. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
5. When RF concentration in the sample is less than 2000IU/ml, the relative deviation of the test results is within ±15%.

【Performance】

1. Limits of detection

No higher than 1.40 ng/mL.

2. Accuracy

The relative deviation from the target value is within ±15%.

3. Precision

The within and between assay coefficient of variations are within 15%.

4. Linear range

Within the linear range (1.40~ 60.00 ng/mL), the linear correlation coefficient R⩾0.990.

【Precaution】

1. This kit is only used for in vitro diagnosis.
2. The test card and sample diluent are disposable and cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃ ~ 30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. The requirements of specimen collection and storage should be strictly observed. If the specimen is turbid, it should be centrifuged and discarded before use.
5. The used kits should be treated as potential infectious substances, and all samples, reagents and potential pollutants should be disinfected and treated according to the relevant local regulations.

【Interpretation of signs】

	Temperature limit		Do not re-use
	Keep away from sunlight	IVD	In vitro diagnostic medical device
	Keep dry		Consult instructions for use

【Reference】

[1] Soi H, Beli I. Separation and identification of steroids produced by fermentative oxidation of progesterone[J]. Fresenius' Zeitschrift für analytische Chemie, 1968, 243(1):291-294.

【Basic Information】

Registrant/Manufacturer: WWHS Biotech.Inc.

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