Diagnostic Kit for Progesterone (fluorescence immunochromatographic assay)

Instructions for Use

INTENDED USE

This kit is applicable to the in vitro quantitative detection of the content of progesterone (PROG) in human serum/plasma/whole blood sample, and mainly used for auxiliary diagnosis of disease associated with abnormal progesterone. The kit only provides the test result of progesterone. The obtained result shall be analyzed in combination with other clinical information. It must only be used by healthcare professionals.

SUMMARY

Progesterone is an important hormone. It plays an important role in regulating menstrual cycle and is vital for maintaining pregnancy. After ovulation, the concentration of progesterone in serum increases quickly. It is a reliable indicator for natural ovulation or ovulation induction.

PRINCIPLE THE DETECTION

This kit uses highly-specificity competitive reaction principle and fluorescent immunochromatographic technology for quantitative detection of content of progesterone (PROG) in human serum/plasma/whole blood samples. The test strip contains the conjugate of progesterone and BSA pre-fixed on the test area (T) of the membrane and goat anti-chicken IgY antibody in the control area (C). The label pad contains pre-coated fluorescently labeled anti-progesterone antibody and chicken IgY antibody. When the sample is tested, the progesterone in the sample binds to the fluorescently labeled anti-progesterone antibody to form an immune complex. By immunochromatographic effect, this immune complex and non-conjugated fluorescent label flow toward absorbent paper along the inside of nitrocellulose membrane. When the complex passes through the test area (T), the non-conjugated fluorescent label will bind with the conjugate coated on the membrane. When passing through the control area (C), the fluorescently labeled chicken IgY antibody binds to the coated goat anti-chicken IgY antibody to form a "goat anti-chicken IgY antibody-fluorescently labeled chicken IgY antibody" complex and agglutinates. The progesterone concentration in the sample is negatively correlated with the fluorescence intensity, and the concentration of progesterone in the sample can be detected by the fluorescence immune analyzer.

MAIN KIT COMPONENTS

Catalogue number	52311101	52311105	52311120	52311125
Components \ specification	1 Tests/Kit	5 Tests/Kit	20 Tests/Kit	25 Tests/Kit
Test device	1	5	20	25
Sample diluents	1	5	20	25
Instructions for Use	1	1	1	1

Note: The volume of sample diluent is 160μL per bottle.

MAIN ACTIVE INGREDIENTS

1 Test line 1 (T): T line area of nitrocellulose membrane is coated with conjugate of progesterone and BSA.

2 Control line (C line): C line area of nitrocellulose membrane is coated with goat anti-chicken IgY antibody.

3 Marking pad: It is coated with fluorescent-microsphere-marker anti-progesterone antibody and chicken IgY antibody.

4 Main component of sample diluent is 20mM, pH7.4 PBS solution.

Warning: The diluent includes 0.1% Proclin300

H317: May cause an allergic skin reaction.

H412: Harmful to aquatic life with long lasting effects.

P280: Wear protective gloves/protective clothing/face protection.

P333+P313: If skin irritation or a rash occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

STORAGE CONDITION

1. The kit should be stored at 2°C~30°C. The shell life of the kit is 24 months.
2. Do not use the kit after the expiration date

APPLICABLE INSTRUMENT

The product can only be used with portable immune analyzer WIZ-A101 of the WIZ BIOTECH.

SAMPLE COLLECTION AND STORAGE

1. This kit is indicated for testing of venous whole blood, serum, and plasma. For whole blood and plasma samples, can use anticoagulant such as EDTA-K2, heparin, and sodium citrate.
2. Any sample taken from human may be infectious and shall be disposed using standard bio-safety procedure.
3. To avoid interfere test result, do not use hyperlipemia, hemolytic or turbid sample.
4. Whole blood collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Whole blood shall be tested as soon as possible after collected. If test cannot be performed in time, the sample shall be stored at 2°C~8°C for up to 2 days.
5. Serum/plasma collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Serum and plasma shall be separated as soon as possible after blood sampling to avoid hemolysis. The separated serum and plasma shall be tested immediately. If test cannot be performed in time, the separated samples can be stored at 2°C~8°C for 7 days, and frozen below -15°C for 6 months.
6. Avoid repeated freezing-thawing of sample. Turbid sample or sample with sediment shall be tested after centrifuged or filtered to clarity.
7. Before test, sample shall restore to room temperature and be well-mixed sufficiently

REAGENT PREPARATION

1. Use immediately after open the aluminum foil bag.
2. Before test, restore the reagent to room temperature.

TEST METHOD

Read the instruction for use and test operation manual completely before the test and restore the reagent to room temperature before the test. Do not perform the test without restoring the reagent to room temperature to avoid affecting the accuracy of the test results.

The following operation steps are all performed provided that WIZ-A101 portable immune analyzer has been ready for use. To select or change any setting of WIZ-A101 portable immune analyzer, please refer to user manual of WIZ-A101 portable immune analyzer.

WIZ-A101 portable immune analyzer has two test modes: I standard test mode; II quick test mode. It is required to select corresponding test mode before test, and then go into the next operation:

I Select standard test mode of WIZ-A101 portable immune analyzer

I-1: Use of portable immune analyzer

(1) Open the aluminum foil bag package of reagent and take out the test device.
(2) Horizontally insert the test device into the slot of immune analyzer.
(3) On home page of operation interface of immune analyzer, click "Standard" to enter test interface.
(4) Click "QC Scan" to scan the QR code on inner side of the kit; input kit related parameters into instrument and select sample type.
Note: Each batch number of the kit shall be scanned for one time. If the batch number has been scanned, then skip this step.
(5) Check the consistency of "Product Name", "Batch Number" etc. On test interface with information on the kit marker.
(6) After information consistency is confirmed, take out sample diluents, add 80μL of serum/plasma/whole blood sample, and sufficiently mix.
(7) Add 80μL of above mixed solution into the sample hole of test device.
(8) After complete sample addition, click "Timing" and remaining test time will be automatically displayed on the interface.
(9) Immune analyzer will automatically complete test and analysis when test time is reached.

I-2: Result calculation and display

After test by immune analyzer is completed, test result will be displayed on test interface or can be viewed through "History" on home page of operation interface.

II Select quick test mode of WIZ-A101 portable immune analyzer

II-1: Drip the sample into the test device

(1) Open the aluminum foil bag package, take out the test device, and horizontally place it on experiment table;
(2) Take out sample diluents, add 80μL of serum/plasma/whole blood sample and mix;
(3) Add 80μL of above mixed solution into the sample hole of test device;
(4) Start stopwatch and wait for 15 minutes.

II-2: Use of portable immune analyzer

(1) After post-sample-addition reaction for 15 minutes, horizontally insert the test device into the slot of immune analyzer;
(2) On home page of operation interface of immune analyzer, click "Quick Test" to enter test interface;
(3) Click "QC Scan" to scan the QR code on inner side of the kit; input kit related parameters into instrument, and select sample type;

Note: Each batch number of the kit shall be scanned for one time. If the batch number has been scanned, then skip this step.
(4) Check the consistency of "Product Name", "Batch Number" etc. On test interface with information on the kit marker;
(5) After information consistency is confirmed, click "Test". The immune analyzer will automatically complete test and analysis.

II-3: Result calculation and display

After test by immune analyzer is completed, test result will be displayed on test interface or can be viewed through "History" on home page of operation interface.

INTERPRETATION OF THE RESULT

Gender		Range (ng/mL)
Male		0.1-0.9
Female	Follicular phase/Ovulatory phase	0.3-1.5
	Luteal phase	5.2-18.5
	Menopause	<0.8

1. For the reference intervals established based on the above data of test kit, it is recommended that each laboratory establish the reference intervals based on the clinical significance of the population in its region.
2. Progesterone concentrations above the reference range should exclude physiological changes or stress response. It is indeed abnormal and should be diagnosed in combination with clinical symptoms.
3. The results of this method are only applicable to the reference range established by this method and are not directly comparable to other methods.
4. Other factors may also cause error in the test result, including technical reasons, operation errors and other sample factors.

*Invalid result: If the assay result is invalid, the WIZ-A101 portable immunoassay analyzer will display an "invalid" result. The test personnel should read the kit instructions and portable immunoassay analyzer instructions carefully and repeat the test. If the "invalid" result is obtained If it reappears, please contact Xiamen Wiz Biotech Co., Ltd.

PRECAUTIONS

1. This kit can only be used for in vitro diagnosis.
2. This kit is for healthcare professionals only.
3. Before test, restore reagent and sample to room temperature.
4. This kit is disposable.
5. Do not use expired reagent.
6. Sample collection and storage must be performed in strict accordance with this instruction.
7. The reagent should be stored in strict accordance with the conditions specified in this instruction for use. Do not store the reagent under freezing condition.
8. Do not open the aluminum foil bags before test and protect the products from moisture; do not use if the aluminum foil bags are damaged or if the test reagents are wet.
9. For all components of the kit, it is recommended not to mix or interchange different batches.
10. Excessive or insufficient sample may lead to deviation of result.
11. Do not confuse sample hole with result observation window. Adding sample to result observation window will make test result invalid.

12. Test method should strictly follow the instruction for use.
13. For specific explanation of test result, analysis shall be performed in combination with clinical information.
14. The used reagent and sample shall be properly disposed as medical waste with risk of biological infection and handled safely.
15. Desiccant in aluminum foil bag is inedible.
16. Sample diluent is only used for test. Do not drink it. Wrong use may lead to biological hazard.
17. During test, test procedure, precautions and result explanation of the reagent must be followed to avoid wrong result.

PRODUCT PERFORMANCE INDEX

Evaluation performed using internal reference material of the enterprise demonstrates that all performance indexes of this kit conform to standard. Specific performance indexes are as below:

1. Reportable range of the reagent (kit): Within 0.5~500 ng/mL.
2. Linear range: Linearity of the reagent (kit) is within 0.5ng/mL~50ng/mL. Analysis performance meets the following requirement:

a) The correlation coefficient (r) of linearity should be ≥0.9900;

3. Accuracy: The recovery rate should be within the range of [85% ~ 115%].
4. Limit of detection: ≤0.3 ng/mL;
5. Repeatability: CV≤15%;
6. Specificity: No cross-reaction phenomenon occurs when the following substances are tested under the shown concentration condition.

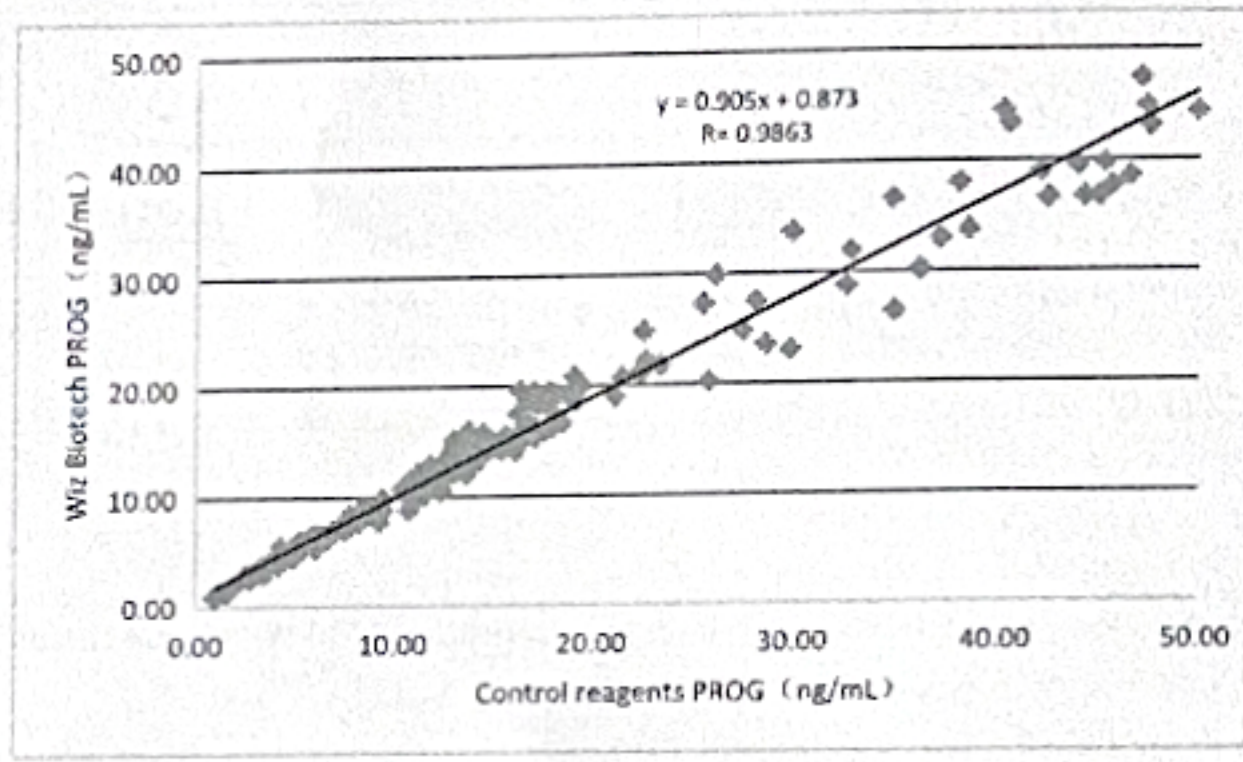
substance	concentration	substance	concentration
E2	500 ng/mL	E3	100 ng/mL
T	500 ng/mL	17β-E2	100 ng/mL
Cor	500 ng/mL	-	-

7. Interfering substance: Following substances are found to cause no interference when they are tested at the given concentration.

Interfering substance	Concentration	Interfering substance	Concentration
Bilirubin	2.0 mg/mL	Hemoglobin	10.0 mg/mL
Triglyceride	40.0 mg/mL	Rheumatoid factor	1500.0 IU/mL

8. Clinical performance

Clinical evaluation performance of the product is assessed through collecting 180 clinical samples. The corresponding kit of listed electrochemiluminescence method is used as the control reagent. The test results are compared, and their comparability is studied with linear regression. The correlation coefficients of the two tests are Y=0.905X+0.873 and R=0.9863, respectively.



LIMITATION

1. This reagent is only used for testing human whole blood, serum, and plasma.
2. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
3. Test shall be carried out at normal room temperature (18℃~25℃).
4. Linearity range of this kit is 0.5~50ng/mL. To measure accurate concentration of high-concentration sample that exceeds measurement linearity range of the kit, measurement and calculation should be performed after dilution to within the linearity range of the kit. Under the conditions of normal saline or sample diluents, the maximum dilution multiple of this kit is 10 times and the reportable range is 0.5~500 ng/mL.
5. Due to low concentration of the analyte, this method cannot detect analyte, will leading to result deviation.
6. Since some non-specific reactions or other cross reactions cannot be fully studied, false positive results may occur in this test.
7. There is a low probability of false positive result in this test. Therefore, all positive results must be verified by other method.
8. If the obtained result is questionable, immediately re-test or use other method to test the sample.
9. Test result of this reagent can only be used as an auxiliary means for doctor or other diagnosis. Test result should be combined with other clinical and laboratory data. If test result is not consistent with clinical evaluation, further examination will be required.

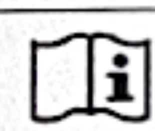
LITERATURE REFERENCES

[1] Taraborrelli S. Physiology, production and action of progesterone. Acta Obstet Gynecol Scand. 2015 Nov;94 Suppl 161:8-16.

[2] Hansen KR, Eisenberg E, Baker V, et al. Midluteal Progesterone: A Marker of Treatment Outcomes in Couples With Unexplained Infertility. J Clin Endocrinol Metab. 2018;103(7):2743-2751.

[3] Leiva R, Bouchard T, Boehringer H, Abulla S, Ecochard R. Random serum progesterone threshold to confirm ovulation. Steroids. 2015 Sep; 101:125-9.

SYMBOLS

Symbol	interpretation	Symbol	interpretation	Symbol	interpretation
	Consult instructions for use		Tests per kit		Manufacturer

WIZ BIOTECH

IVD	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
2°C–30°C	Store at 2°C~30°C	REF	Catalogue number	LOT	Batch code
EC REP	Authorized Representative in the European Community		Caution		

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