QASSAY

QASSAY Progesterone Rapid Test

FOR PROFESSIONAL USE IFA-PROG-0011

PACKAGING SPECIFICATIONS
24 Tests/Kit

INTENDED USE

This kit is suitable for in vitro quantitative detection of progesterone concentration (PROG) in human serum, plasma, or whole blood.
Progesterone, a gestagenic steroid hormone, is formed primarily in the cells of the corpus luteum and, during pregnancy, in the placenta. Progesterone concentration correlates with the development and regression of the corpus luteum. While progesterone is barely detectable in the follicular phase of the female cycle, an increase in progesterone levels is seen one day before ovulation. Increased progesterone synthesis occurs during the luteal phase. In the second half of the cycle, pregnanediol is excreted in the urine as the main breakdown product of progesterone. Progesterone induces the conversion of the uterine mucosa into gland-rich tissue during the secretion phase, preparing the intrauterine implantation of the fertilized egg. During pregnancy, progesterone inhibits the contraction of the myometrium. In the mammary gland, progesterone (along with estrogen) promotes the proliferation, secretion, and disposition of the alveoli. Progesterone screening is used in fertility diagnosis for ovulation screening and luteal phase assessment.

PRINCIPLE OF THE PROCEDURE

This test kit uses a competitive principle and fluorescence immunochromatography analysis technology to quantitatively detect the concentration of PROG in human serum, plasma, or whole blood samples.
The lyophilized powder of this product contains fluorescent microspheres with anti-PROG antibodies and chicken anti-IgY antibodies, and the test line and nitrocellulose membrane control line are coated with PROG antigen and chicken IgY, respectively. When the sample is analyzed, the PROG antigen from the sample will combine with the fluorescent bead-labeled mouse anti-PROG antibody embedded in the lyophilized powder to form a fluorescent bead-labeled anti-PROG antibody immune complex. Under the action of chromatography, the immune complex flows along the nitrocellulose membrane to the end of the absorbent filter paper. As there are no more PROG antibody binding sites, the immune complex cannot be captured by PROG antigens that have been previously coated on the test line. However, the excess of unbound fluorescent microspheres of the mouse anti-PROG antibody is captured by the PROG antigens that have been pre-coated. Therefore, the more PROG there is in the sample, the less fluorescent bead-labeled mouse anti-PROG antibody will be enriched at the test line. When the samples pass through the control line, the fluorescent particle-labeled anti-chicken IgY antibody is enriched by combining it with the pre-coated chicken IgY antibody. The concentration of PROG in the sample is negatively correlated with the fluorescence intensity of the test line. The concentration of PROG in the sample is obtained by testing and analysis using the immunofluorescence analyzer.

COMPONENTS

Main components (ref. IFA-PROG-0011):
The product is mainly composed of the following items:

Pouch (test card and desiccant)	24 tests
Sample Diluent	1 unit
Freeze-dried powder	24 units
Pipette tip	24 units
Directions for use	1 unit

Note: The components of the different batches of kits are not interchangeable.
Materials Required, but Not Provided:

- Qassay Lateral Flow Reader (ref. Q1A-DUO-USB)
- Transfer pipette
- Sample Collection Containers
- Timer (Quick Test Mode)

STORAGE AND STABILITY

1. The test kit should be stored at 2°C~30°C in a cool, dark and dry place, valid for 18 months; Do not freeze or use after the validity period by all means. Keep away from direct sunlight, moisture, and heat.
2. The test card should be used within 60 minutes of removing the foil bag.
3. The sample diluent should be used immediately after breaking the seal.
4. MFD date and CAD date marked on the label.

SAMPLE COLLECTION AND STORAGE

1. Applicable to serum, plasma and whole blood samples. Commonly used clinical anticoagulants (sodium heparin, EDTA, or sodium citrate) have no effect on the screening results of this kit.
2. Specimens should be collected according to routine clinical methods and hemolysis should be avoided.
3. If fresh serum or plasma samples are not tested immediately, they should be stored at 2°C~8°C and tested within 7 days. For long-term storage, freeze at -20°C. Avoid freezing and thawing repeatedly.
4. Whole Blood Sample Collection: Collect venous blood with vacuum disposable blood collection containing anticoagulant without separation and directly as a test sample. Whole blood samples can be stored at 2°C~8°C in the refrigerator, not frozen, and tested within 5 days of collection.
5. The sample stored at low temperature should be balanced at room temperature prior to testing.
6. Obvious samples of hemolysis, lipemia, and jaundice should not be used.

TEST PROCEDURE

Download the app from the Google Play Store or Apple Store and sign in with your credentials. If sign up is needed, please contact your distributor. For specific operation of the instrument, follow the instructions on the reader.

Step 1: Preparation
The test and blood sample should be balanced at room temperature before the test. Open the foil bag, take out the test card, and place it on a table.
New Test: Select the New Test mode, scan the QR code located in the test and follow the procedure. Select Patient ID, Sample ID, and sample type (if applicable).
Quick Test: Select the Quick Test mode, connect the device and scan the QR code on the test. Select Patient ID, Sample ID, and sample type (if applicable).
Step 2: Sampling
Draw 60 µL of serum, plasma, or whole blood and 60 µL of sample diluent into the freeze-dried powder tube. Be careful not to inhale air bubbles.
Step 3: Mix
Close the test tube and shake for 60 seconds to completely dissolve again and mix the freeze-dried powder.
Step 4: Loading
Pipette 100 µL of sample mixture and load it into the sample well of the test card.
Step 5: Testing
New Test: Press Start Timer button and wait for the 10 minutes reaction time. A timer will be displayed on screen. The Qassay shall be connected to the Mobile App before this timer has expired.
Quick Test: Wait for 10 minutes with an external timer.
Insert the test into the Qassay. Once inserted, the animation on the Qassay App will change and you will be requested to extract the test at a constant speed. After some seconds, the test result will be displayed. If asked to repeat the reading, follow the feedback warning for proper action. If the test is not processed within 3 minutes after the countdown concludes, the test will be considered invalid, and a new test must be used for retesting.

CALIBRATION

Traceability: Calibrators for calibration curve setting are traceable to internal reference standards. This method has been standardized against Roche Elecsys progesterone.
The calibration curve of the reagent is integrated into the identification chip. The fluorescence analyzer replaces the test signal from the sensing card on the calibration curve to calculate the concentration of PROG in the sample.

INTERPRETING TEST RESULTS

Gender	Phase	Range (ng/mL)
Male	/	0.2 — 1.5
Female	Follicular phase	0.2 — 1.5
	Ovulatory phase	0.8 — 3.0
	Luteal phase	1.7 — 27.0
	Postmenopausal	0.1 - 0.8
	First trimester	9.0 — 47.0
	Second trimester	17.0— 46.0
	Third trimester	55.0-255

QUALITY CONTROL

This product used in conjunction with the lateral flow reader contains internal control for routine quality control requirements. This internal control is carried out every time a patient sample is analyzed. This check indicates whether the test cartridge was inserted and read correctly by the lateral flow reader. An invalid internal control result causes an error message in the analyzer indicating that the test should be repeated.

LIMITATIONS

1. Positive results from this reagent can only be used as a basis for diagnosing diseases. It is suggested to confirm the diagnosis by combining other pathologic features and testing methods.
2. This reagent is suitable for detection in human serum, plasma or whole blood samples, the results will be erroneous in other types of samples.
3. The reagent is used to detect the concentration of progesterone by immunological principle. The temperature will affect the results. The reagent should be balanced at room temperature before use after cryopreservation. Direct use of cryogenic reagents will affect the test results.
4. This reagent is used to quantitatively detect the concentration of progesterone and the test reagent, ID card and corresponding instrument should be used together. Make sure the test reagent lot number and ID card are the same before use. The instrument is the applicable model and the correct test result cannot be obtained after exceeding the expected use.
5. Different batches of sample diluents cannot be mixed.
6. Improper operation and other factors can affect the accuracy of the results-
7. False-positive results may be due to (i) cross-reactivity between some components of the serum with the capturing/detecting antibodies and/or (ii) nonspecific adhesion of certain components with similar epitopes to bind to these antibodies. In the case of false negatives, the most common factors are: the non-response of the antigens to the antibodies as a result of the antigens

being masked by some unknown components, so that the antigens cannot be detected or captured by the antibodies; instability or degradation of PROG antigens due to time and/or temperature, making them unrecognizable by antibodies; and reduce the quality of other test components. The effectiveness of the test is highly dependent on the storage of the kit and the sample in optimal conditions.
8. As with all diagnostic reagents, the final diagnosis should be made by the physician after the combination of several clinical indicators and symptoms.

PRODUCT PERFORMANCE INDEX

In-house calibration products were used for evaluation, and the kit's performance indicators met the standards. The specific performance indicators are as follows:
1. Linearity range: PROG 0.5 ng/mL — 60 ng/mL, linear correlation coefficient (r) ≥ 0.9900
2. Accuracy: The relative deviation of the kit's accuracy is within ± 1.5%.
3. Detection limit: 0.5 ng/mL.
4- Repeatability and reproducibility: CV ≤ 15%.
5. Interferences: no interferences of bilirubin ≤ 12 mg/mL, hemoglobin ≤ 6 mg/mL, and triglycerides ≤ 15 mg/mL have been found

PRECAUTIONS

1. The reagent is a disposable in vitro diagnostic reagent, which is only used for the detection of human serum, plasma, or whole blood samples. The operation must be carried out strictly in accordance with the instructions. Do not use expired and damaged products.
2. The kit should be sealed and kept away from moisture. Reagents or samples stored at low temperature must be balanced at room temperature before they can be used.
3. If clinical specimens need to be frozen at -20°C or below, it is recommended that the freezing storage time should not exceed three months, and that repeated freezing and thawing should not exceed three times.
4. The reagents should be used as soon as possible after removing them from the foil bag, to avoid exposure to air for too long and affect test results due to moisture.
5. Do not use samples that have been in place for too long, bacteria and odor.
6. Operate according to laboratory testing procedures for infectious diseases. Waste should be disposed of as if it were infectious.
7. Improper operation can affect the accuracy of the results, such as insufficient sample mixing, incorrect amount of sample addition, wet viewing window or inaccurate detection time, etc.
8. If you have any questions, please contact the manufacturer or authorized representative.

BIBLIOGRAPHY

1. Potential use of single measurement of serum progesterone in detecting early pregnancy failure Hanita O MD, MPATH, Hanisah AH MD, MPATH.
2. Metabocard for Hydroxyprogesterone. Human Metabolome Database. Retrieved 31 July 2013.
3. Progestin regulation of cellular proliferation. Clark CL and Sutherland RL. Endocrine Review 1990; 11: 266-301.
4. Physiological Action of Progesterone in Target Tissues. Graham JD and Clarke CL. Endocrine Reviews 1997; 18: 502-519.
5. Progesterone, progestagens and the central nervous system. Hum Reprod Genazzani AR, Stomati M, Morittu A, Bernardi F, Monteleone P, Casarosa E, Gallo R, Salvestroni C and Luisi M. 2000; 15: 14-27.
6. Sex steroids and bone: current perspectives. Hum reprod update. Balasch J. 2003; 9: 207- 22.
7. Simultaneous Radioimmunoassay of Plasma FSH, LH, Progesterone, 17-Hydroxyprogesterone, and Estradiol-17 beta During the Menstrual Cycle. Abraham GE, Odell WD, Swerdloff RS, Hopper K. J Clin Endocrinol Metab, 1972; 34:2, 312—318.
8. Studies on the Pattern of Circulating Steroids in the Normal Menstrual Cycle. Aedo AR, Núñez M, Landgren BM, Cekan SZ, Diczfalus, and E. Circadian Variation in Theperi- Ovulatory Period. Acta Endocrinol (Copenh), 1977; 84:2, 320-332.
9. Hormonal Profile of the Cycle in 68 Normally Menstruating Women. Landgren BM, Unden AL, and Diczfalusy E. Acta Endocrinol (Copenhagen), 1980; 94:1, 89-98.
10- Normal Ovarian Function. Erickson GG. Clin Obstet Gynecol, 1978; vol. 21 No.1, 31-53.
11. Physiological Profiles of Episodic Progesterone Release During the Midluteal Phase of the Human Menstrual Cycle: Analysis of Circadian and Ultradian Rhythms, Discrete Pulse Properties, and Correlations with Simultaneous Luteinizing Hormone Release. Veldhuis JD, Christiansen E, Evans WS, Kolp LA, Rogol AD, Johnson ML. J Clin Endocrinol Metab, 1988; 66:2, 414-421.
12. Neuroendocrine Regulation of the Corpus Luteum in the Human. Evidence for Pulsatile Progesterone Secretion. Filicori M, Butler JP, Crowley WF Jr., J Clin Invest, 1984; 73:6, 1638-1647.
13. The Pattern of Luteal Phase Plasma Progesterone and Estradiol in Fertile Cycles. Laufer N, Navot D, Schenker JG. Am J Obstet Gynecol, 1982; 143:7, 808-813.
14. Method for Monitoring Plasma Progesterone Concentrations in Pregnancy. Winkel P, Gaede P, Lyngbye J Clin Chem 1976; 22:4, 422-428.
15. The Applications of Steroid Hormone Radioimmunoassays to Clinical Obstetrics. Buster JE, Abraham GE. Obstet Gynecol, 1975; 46:4, 489-499.
16. National Institute of Health. Historical reference range of progesterone. http://cclnprod.cc.nih.gov/dlm/testguide.nsf/Index/CB2689.

REVISION HISTORY

Revision	Date	Description
To	07/01/2025	Creation

CE	This product meets the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices
IVD	*In vitro* diagnostic medical device
LOT	Lot Code
	Expiration Date
	Do not use if the package is damaged and refer to *the instructions for use*
	Do not reuse
	Legal Manufacturer
	Caution
2°C 30°C	Store at 2°C~30°C
	See Instructions for Use
EC REP	Authorised representative of the European Community
REF	Catalog Number
Σ	Contains enough for <n testing>
	Keep out of sunlight
	Keep dry
	Date of manufacture
	Importer

Shenzen Sekbio Co., Ltd.
Floor 10, Building 3, Nam Tai Inno Park, Guangming District, Shezen, China 518107
Tel: +86 755 281955562
Email: info@sekbio.com
Website: www.sekbio.com

EC REP
MedUnion S.l.
Carrer de Tapioles, 33, 2-1 Barcelona, 08004, Spain
Tel.: (+34) 644173535
E-mail: rep@themedunion.com

P4Q Health S.L.U.
Calle Nuestra Señora de la Guía, 19, Alonsotegi, 48810
Vizcaya, Spain
Tel.: (+34) 94 498 2029
E-mail: nchealth@p4q.com
Website: www.p4q.com

CE IVD