Diagnostic Kit for Progesterone

A test for the auxiliary diagnosis of threatened abortion in clinical by measuring Progesterone in serum or plasma with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

PACKING SPECIFICATION
25 Tests/ Kit (07PROG5025)

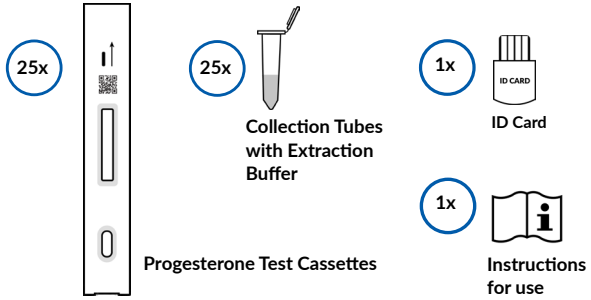
INTENDED USE
The Progesterone (P4) Test Cassette (Serum/Plasma) is based on Fluorescence Immunoassay for the quantitative determination of Progesterone in serum, plasma by using Immunofluorescence Analyzer, and it is clinically mainly used for auxiliary diagnosis of threatened abortion in clinical. The test is intended for healthcare professionals use.

SUMMARY
Progesterone also known as P4 (pregn-4-ene-3, 20-dione) is a C-21 steroid hormone involved in the female menstrual cycle, pregnancy (supports gestation) and embryogenesis of humans and other species.[1]
Progesterone is essential for the regulation of normal female reproductive functions. The major physiological actions of progesterone are: a) in the uterus and ovary: induction of ovulation, facilitation of implantation, and maintenance of early pregnancy; b) in the mammary gland: lobular-alveolar development in preparation for milk secretion; c) in the brain: neurobehavioral expression associated with sexual responsiveness and d) in the bone: prevention of bone loss.[2]
During the follicular phase of the cycle, progesterone levels remain low.[3] Following the LH surge and ovulation, luteal cells in the ruptured follicle produce progesterone in response to LH. During this, the luteal phase, progesterone rises rapidly to a maximum of 10-20 ng/mL at day 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 due to the regression of the corpus luteum.[3] If conception occurs, the levels of progesterone are maintained at mid-luteal levels by the corpus luteum until about week six. At that time the placenta becomes the main source of progesterone and levels rise from approximately 10-50 ng/mL in the first trimester to approximately 50-280 ng/mL in the third trimester.[3,4,5.]

PRINCIPLE
The Progesterone (P4) Test Cassette (Serum/Plasma) detects progesterone based on Fluorescence Immunoassay. The specimen moves through the strip from sample pad to absorbent pad. Progesterone in the specimen will compete with the Progesterone antigen coated on the membrane with the progesterone antibody labeled with fluorescent microspheres. The less Progesterone in the specimen, the more chance that fluorescent microspheres-conjugated anti-Progesterone antibodies can be captured by the Progesterone antigen coated on the membrane (Test line). The concentration of Progesterone in the specimen is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of Progesterone in the specimen can be calculated by Analyzer to show Progesterone concentration in specimen.

REAGENTS
The test include anti-Progesterone antibody coated fluorophore and progesterone antigen coated on the membrane.

MATERIALS PROVIDED



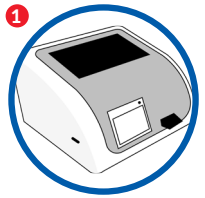
MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Centrifuge
- Specimen Collection Containers
- Timer

PRECAUTIONS
1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Progesterone (P4) Test Cassette should only be used with the Analyzer by approved medical professionals.

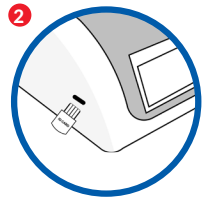
STORAGE AND STABILITY
1. The test should be stored at 4 - 30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the test from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SAMPLE COLLECTION AND PREPARATION
1. Collect the specimens according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and Plasma specimens may be stored at 2 - 8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens. Only clear, non-hemolyzed specimens can be used.
4. EDTA can be used as the anticoagulant tube for collecting the blood specimen.

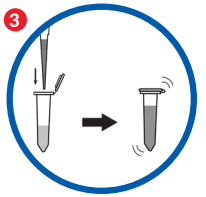
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



Turn on the Analyzer power.

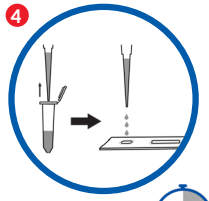


Take out the ID card and insert it into the ID Card Slot. Choose test mode and/or sample type according to needs.

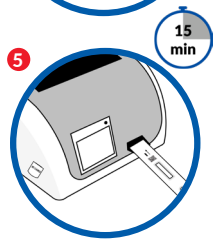


Pipette **75 µL of serum or plasma** into the specimen collection tubes with buffer, mix specimen and buffer well.

Note: The diluted specimen can then be used immediately or stored for up to 4 hours at 2 - 8 °C.



Pipette **75 µL of diluted specimen** into the sample well of the cassette. Start the timer at the same time.



Test results should be interpreted at 15 minutes with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information. Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS
The default result unit of this product is ng/mL, the result can be converted to nmoL/L by the following formula: test concentration in (ng/mL) * 3.18 = result concentration in (nmoL/L).
Results read by Immunofluorescence Analyzer.
The result of tests for Progesterone is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyze. Assay range of Progesterone is 1.4~60 ng/mL.

QUALITY CONTROL

Each Progesterone (P4) Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an "N/A" message on Immunofluorescence Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Progesterone (P4) Test Cassette (Serum/Plasma) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of Progesterone.
2. The results of Progesterone (P4) Tests are based on measuring the levels of Progesterone in a specimen. It should not be used as the sole criterion for treatment decisions. Other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

Gender	Phase	(ng/mL)
Male	/	<1.4 ~ 1.5
Female	Follicular Phase	1.4 ~ 1.9
	Ovulatory Phase	1.4 ~ 12.0
	Luteal Phase	3.0 - 30
	Postmenopausal	1.7 ~ 28.7
	Pregnancy period (<12 weeks)	11.0 ~ 53.0
	Pregnancy period (12 weeks~24weeks)	21.5 ~ 60.0

Note: Due to differences in geography, race, environment, gender, etc., each laboratory should establish its own reference interval.

PERFORMANCE CHARACTERISTICS

1. Accuracy

The product was evaluated with 80 clinical specimens compared with a product using the same methodology on the market, and the correlation coefficient (r) was 0.975.

2. Analytical sensitivity

The Progesterone (P4) Test Cassette (Serum/Plasma) can detect levels of testosterone as low as 1.4 ng/mL in serum, plasma.

3. Linearity Range

1.4 ~ 60 ng/mL, R≥0.990

4. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 2.0 ng/mL, 10.0 ng/mL of Progesterone. C.V. is ≤15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 2.0 ng/mL, 10.0 ng/mL of Progesterone. C.V. is ≤15%.

BIBLIOGRAPHY

1. Metabocard for Hydroxyprogesterone. Human Metabolome Database. Retrieved 31 July 2013.
2. Sex steroids and bone: current perspectives. Hum reprod update. Balasch J. 2003; 9: 207-22.
3. 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.
4. Method for Monitoring Plasma Progesterone Concentrations in Pregnancy. Winkel P, Gaede P, Lyngbye J Clin Chem 1976; 22:4,422-428.
5. The Applications of Steroid Hormone Radioimmunoassays to Clinical Obstetrics. Buster JE, Abraham GE. Obstet Gynecol, 1975; 46:4, 489-499.

SYMBOLS

	Consult Instructions For Use	REF	Catalogue Number
IVD	For *In-vitro* Diagnostic use	EC REP	Authorized Representative
4℃ 30℃	Store at 4 °C ~ 30 °C		Do Not Reuse
	Keep away from Sunlight		Do Not Use if Package is Damaged
LOT	Lot Number	CE	European Conformity
	Manufacturer		Date of Manufacture
	Expiration Date	Σ	Tests per Kit
UDI	Unique Device Identifier		

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Rev: 07PROG5025-014-03-42-EN
Effective date: 22.03.2024