Progesterone FIA Rapid Test

(Serum/Plasma)

FIA-PRO-001

A rapid test for detecting Progesterone in serum or plasma with the use of the Biopanda Fluorescence Immunoassay Analyser.
For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda Progesterone FIA Rapid Test is based on Fluorescence Immunoassay for the quantitative determination of Progesterone in serum or plasma to aid as an indicator of fertility.

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 luteinising hormone (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 on the day following ovulation. During the luteal phase, progesterone transforms the estrogen-primed endometrium from a proliferative to a secretory state.[8] 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 FIA Rapid Test Cassette detects Progesterone based on Fluorescence Immunoassay. Progesterone in the specimen will compete with the Progesterone antigen coated on the membrane with the progesterone antibody labelled 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 sample can be calculated by the Biopanda Fluorescence Immunoassay Analyser to show Progesterone concentration in specimen.

REAGENTS

The test kit includes anti-Progesterone antibody coated fluorophores and Progesterone antigen coated on the membrane.

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 Biopanda Progesterone FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyser by approved medical professionals.

STORAGE AND STABILITY

1. The kit 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 kit from contamination. 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.

KIT COMPONENTS

- 10 x foil wrapped Progesterone test cassettes
- 10 x Specimen collection tubes with dilution buffer
- 1 x ID card (Progesterone)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Analyser

SPECIMEN COLLECTION AND PREPARATION PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it.

SPECIMEN COLLECTION AND PREPARATION

1. Collect the specimen 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 1 day, 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.
4. EDTA can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. Transfer **75 µL of serum or plasma** to the buffer tube with a micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 4 hours at 2-8°C.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Analyser Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select “Standard test” or “Quick test” mode.
2. Take out the ID card and insert it into the Analyser port.
3. **Serum/plasma**: Transfer 75 µl of serum/plasma into the buffer tube, mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette**: Pipette 75 µl of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Analyser; Standard Test mode and Quick Test mode. Please refer to the

user manual of the Biopanda Fluorescence Immunoassay Analyser for details.

"Quick test" mode: Insert the test cassette into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.

"Standard test" mode: Insert the test cassette into the Analyser immediately after sample application, click "New test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for Progesterone is calculated by the Biopanda Fluorescence Immunoassay Analyser and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser.

Linearity range of the Biopanda Progesterone FIA Rapid Test is 1.4~60 ng/ml.

QUALITY CONTROL

Each Biopanda Progesterone FIA Rapid Test Cassette contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Analyser. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Analyser indicating that the test should be repeated. 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 Biopanda Progesterone FIA Rapid Test Cassette is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Progesterone.
2. The Biopanda Progesterone FIA Rapid Test Cassette will only indicate the presence of Progesterone in the specimen and should not be used as the sole criterion for clinical decisions.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED RESULTS

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 intervals.

PERFORMANCE CHARACTERISTICS

ACCURACY: The product was compared with 80 clinical specimens in a kit with the same methodology on the market, and the correlation coefficient (r) was 0.975.

ANALYTICAL SENSITIVITY

The Biopanda Progesterone FIA Rapid Test can detect levels of progesterone as low as 1.4 ng/ml in serum and plasma.

LINEARITY RANGE: 1.4~60 ng/mL, R≥0.990

PRECISION

INTRA-LOT PRECISION

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

REFERENCES

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

Index of Symbols

	Manufacturer	Σ	Tests per kit	2	Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
4°C 30°C	Store between 4-30°C	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's Progesterone FIA Rapid Test. Please read this manual carefully before operating to ensure proper use.

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