Cat No.: SF098-01

Progesterone Rapid Test Kit

In vitro Diagnostics

INTENDED USE

The SENSIT Progesterone Rapid Quantitative Test is a fluorescence immunoassay used along with SENSIT FIA System for quantitative determination of progesterone concentration in human whole blood, serum or plasma specimen. The test is used as an aid to track ovulation, monitor the effect of progesterone therapies and in early pregnancy to help diagnose an ectopic or failing pregnancy.

For in vitro diagnostic use only. For professional use only.

SUMMARY

Progesterone is a female hormone produced by the ovary. It is important for the regulation of ovulation and menstruation of human.

During the follicular phase of the menstrual cycle, progesterone levels remain low. Following the LH surge and ovulation, luteal cells in the ruptured follicle produce progesterone in response to LH thus the progesterone level rises rapidly at day 5-7 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.

If the conception occurs, during the first trimester the ovaries will produce progesterone maintaining at mid-luteal level to help build and maintain the lining of the uterus to allow a fertilized egg to implant until the placenta takes over the function around the 9-10th week of pregnancy.

TEST DESCRIPTION & PRINCIPLE

The test uses a competitive immune detection method; In this method, the target material in the sample bind to the fluorescence (FL)-labeled detection antibodies in the detection buffer, to form the complex as sample mixture. This complex is loaded to migrate onto the nitrocellulose matrix, where the covalent couple of progesterone and bovine serum albumin (BSA) is immobilized on the test strip, and interferes with the binding of target material and FL-labeled antibody. If the more target material exists in blood, the less detection antibody is accumulated, resulting in the less fluorescence signal.

MATERIALS PROVIDED

Components of SENSIT Progesterone

1. Cartridges
2. ID Chip
3. Instruction For Use
4. Detection Buffer tubes

STORAGE & STABILITY

1. The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4-30 °C.
2. The detection buffer pre-dispensed in a tube is stable for 20 months if stored at 2-8 °C.
3. After the cartridge pouch is opened, the test should be performed immediately.

.

SAMPLE COLLECTION & PREPARATION

The sample type for SENSIT Progesterone is human serum /plasma.

1. To avoid time related absorption, serum samples should not be stored in collection tube with gel separators.
2. It is recommended to test the sample within 24 hours after collection.
3. The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
4. Samples may be stored for up to a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, samples should be frozen at -20 °C.
5. Samples stored frozen at -20 °C for 2 months showed no performance difference.
6. Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change of test values.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only. Do not swallow.
2. Lot Number of all the test components (test device, ID chip and buffer) must match each other. Do not mix components from different kit lots.
3. Inspect the packaging and labels before use. Do not use if the pouch is broken, torn or not well sealed, or the vial looks damaged or leaked.
4. Carefully follow the instructions and procedures described in this insert.
5. Do not use the test device beyond the expiration date. The test device must remain in its original sealed pouch until ready to use.
6. A buffer tube should be used for processing one sample only.
7. The operation shall be conducted away from vibration and magnetic field. SENSIT FIA System may generate minute vibration during use, which should be regarded as normal.
8. One pipette tip should be used for one specimen only.
9. Do not touch the test area of the test device

All specimens and used test materials are considered as potentially infectious. The used pipette tips, buffer tubes, test devices and specimens must be handled carefully and disposed of in accordance with local regulations and procedures.

TEST PROCEDURE

1. Transfer 30 µL (Human serum/plasma/control) of sample using a transfer pipette to a tube containing the detection buffer.
2. Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
3. Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4. Insert the sample-loaded cartridge into the slot of the i-Chamber or an incubator (25 °C).
5. Leave the sample-loaded cartridge in the i-Chamber or an incubator for 15 minutes.
6. For scanning the sample-loaded cartridge, insert it into the test cartridge holder the Fluoroscence immunoassay analyser. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.
7. Press 'Select' button on the Fluoroscence immunoassay analyser to start the scanning process.
8 Fluoroscence immunoassay analyser will start scanning the sample-loaded test cartridge immediately.
9. Read the test result on the display screen of the Fluoroscence immunoassay analyser.

EXPECTED VALUE AND RESULT INTERPRETATION

Fluoroscence immunoassay analyser calculates the test result automatically and displays progesterone concentration of the test sample in terms of nmol/L and ng/mL.

	Type	Mean (nmol/L)	Range(nmol/L)
Non pregnant females	Males	2.67	0.46-6.55
	Mid follicular phase	2.19	0.99-4.83
	Mid luteal phase	36.32	16.4-59.02
	Post menopausal	0. 0.80	<0.25-2.48
Pregnancy	First trimester	70.50	15.40-161.35
	Second trimester	94.54	61.72-144.05

*SI : nmol/L = 3.18 X ng/mL

- Working range : 4.45-127.2 nmol/L and 1.4-40 ng/mL

References

1. Progestin regulation of cellular proliferation. Clark CL and Sutherland RL. Endocrine Review 1990;11: 266-301.
2. Physiological Action of Progesterone in Target Tissues. Graham JD and Clarke CL. Endocrine Reviews 1997;18: 502-519.
3. 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.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in SENSIT FIA test for single-step *in vitro* quantification of progesterone are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use.

ubio Biotechnology Systems Pvt Ltd
Plot # 15A,Biotechnology Zone
Kalamassery, Cochin, Kerala, India 683503
Ph:, +91-484-2970043
http://www.ubio.in
e-mail: contact@ubio.co.in

UBD/QA/IFU/ SF098-01
Rev. No: A1.1/13-02-2025