



Prog Fast Test Kit (Immunofluorescence Assay)

IF1071 for Getein 1100
IF5071 for Getein 1160
IF3071 for Getein 1180
IF2071 for Getein 1600
IF4071 for Getein 1200



Instructions for Use

INTENDED USE

Prog Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of progesterone in human serum and plasma samples. The test is used clinically as an aid in the diagnosis of diseases related to abnormal progesterone levels, such as threatened miscarriage and luteal phase defect. For professional and laboratory use only.

SUMMARY

Progesterone (P) is a steroid hormone secreted by the corpus luteum of the ovary, and its level varies with the physiological cycle, which is important for ovulation detection, luteal function, normal pregnancy, and placental function. Progesterone is secreted by the ovaries and adrenal glands in non-pregnant women, and the level of progesterone is very low in the follicular phase. After ovulation, the corpus luteum of the ovary produces a large amount of progesterone, which peaks 8-9 days after ovulation and then declines rapidly to follicular phase levels about 4 days before the next menstrual period. If the level of progesterone in the luteal phase is significantly lower than the physiologic value, it suggests possible luteal insufficiency. In early pregnancy, progesterone is secreted by the corpus luteum of pregnancy and serum progesterone levels continue to rise. If the corpus luteum secretes low levels of progesterone during this period, preeclampsia is likely to occur. After 8-10 weeks of pregnancy, the placenta replaces the corpus luteum as the main secretory gland of progesterone, and at this time, the level of progesterone is stable and gradually increases, if the serum progesterone level drops significantly during this period, suggesting that the placenta may be functionally impaired. Progesterone levels will be higher in late pregnancy.

During a woman's pregnancy, progesterone provides support and security for the early growth and development of the fetus. Progesterone levels have a close relationship with the activity of the pregnancy, and low levels of progesterone often indicate an abnormal pregnancy, and can even lead to miscarriage. Determination of progesterone in the blood is clinically important for regulating the female menstrual cycle, detecting luteal function and maintaining pregnancy.

PRINCIPLE

Prog Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a competitive design. After the sample has been applied to the test strip, the fluorescence-labelled progesterone monoclonal antibody binds with the progesterone in sample and forms a marked antigen-antibody complex. Meanwhile, the uncombined fluorescence-labelled progesterone monoclonal antibody binds with the progesterone antigen on the test line. The fluorescence intensity of the test line decreases in proportion to the amount of progesterone in sample. Fluorescent signals intensity can be analyzed by applicable device thus the progesterone in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
Prog test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 pcs	25 pcs	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*Prog test card

A test card main consists of: Fluorescence-labelled prog monoclonal antibody and prog antigen.

**Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 0.2 mL contained in each tube consists of:

- Sample diluent main contains phosphate buffer (20 mmol/L), NaN_3 (<0.1%).

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box main consists of:

- Phosphate buffer (20 mmol/L), NaN_3 (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

- Box with pipette tips (96 tips/box),

- Mixing plate (1 piece/box)

Note:

- The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
- Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches or the cartridge until ready to perform the test.
- Do not reuse the test card or pipet.
- Handle all specimens as potentially infectious. Proper

handling and disposal methods should be followed in accordance with local regulations.

- Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for **serum and plasma samples**.
- Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma samples.
- It is recommended to test the sample within 4 hours after collection. If testing is delayed, serum and plasma samples are stable for 5 days when stored at 2~8°C and 6 months when stored at -20°C.
- Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples or hemolysis samples.
- Sample volume (**Getein 1100/Getein 1160/Getein 1180**): 100 μL .

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette to drop 100 μL of sample into one tube of sample diluent, mix gently and thoroughly, then add 100 μL of sample mixture into the sample well on the test card.
- Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4. Use disposable pipet or pipette to drop 100 µL of sample into one tube of sample diluent, mix gently and thoroughly, then add **100 µL** mixture into the sample well on the test card.
5. Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
3. Make sure the insertion of test card and the sample are correct and complete.

RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/ Getein 1180/Getein 1200/Getein 1600.

Prog Fast Test Kit (Immunofluorescence Assay) results are provided in ng/mL.

LIMITATIONS

1. The test results of this reagent are for clinical reference only, and cannot be used as the basis for diagnosis or exclusion of cases alone additional tests should be performed accordingly.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	25 g/L
Bilirubin	0.1 g/L

EXPECTED VALUE

The expected normal value for Progesterone was determined by testing blood samples from apparently healthy individuals. Reference range of Progesterone:

Group		n	95% Reference range (ng/mL)
Healthy men		200	0.15-1.97
Healthy women	Follicular phase	121	0.34-1.52
	Luteal phase	58	5.20-18.76
	Post menopause	156	0.12-0.76
Healthy pregnant women	1 st trimester	135	4.73-50.21
	2 nd trimester	49	19.27-45.34

It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

1. Measuring Range 0.10–40.00 ng/mL
2. Limit of Detection ≤0.10 ng/mL
3. Within-Run Precision ≤10%
4. Between-lot Precision ≤15%

REFERENCES

1. Julia S, R J W, Pawel B, et al. Role of progesterone and

- progesterin therapy in threatened abortion and preterm labour[J]. *Frontiers in bioscience: a journal and virtual library*, 2008, 13:1981-90.
2. Julia S. Progesterone orchestrates foetal-maternal interactions in pregnancy[J]. *Journal of Reproductive Immunology*, 2023, 159.
 3. Clinical and Laboratory Standards Institute. Protocols for determination of limits of quantitation; approved guideline-second edition, EP17-A, CLSI,2004.
 4. Clinical and Laboratory Standards Institute. Evaluation of precision performance of quantitative measurement method; approved guideline-second edition, EP17-A, CLSI,2004.
 5. National Committee for Clinical Laboratory. Method comparison and bias estimation using patient samples; approved guideline. EP9-A2, NCCLS, 2002.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Prog Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/ European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

Thank you for using Prog Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

 Getein Biotech, Inc.
 Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
 Tel: +86-25-68568508
 Fax: +86-25-68568500
 E-mail: tech@getein.com.cn
 overseas@getein.com.cn
 Website: www.getein.com

 CMC Medical Devices & Drugs S.L.
 Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain
 Tel: +34951214054