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# Prog
# Fast Test Kit
# (Immunofluorescence Assay)

IF1071 for Getein1100
IF5071 for Getein1160
IF3071 for Getein1180
REF IF4071 for Getein1200
IF2071 for Getein1600

**User Manual**

## INTENDED USE

Prog Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of progesterone (Prog) in human serum and plasma samples.
Progesterone tests are used to measure ovarian function and can determine if a woman has ovulated and when the ovulation occurred.

## SUMMARY

Progesterone is an endogenous steroid and progestogen sex hormone involved in the menstrual cycle, pregnancy, and embryogenesis of humans and other species.
Progesterone is produced by a woman's ovaries throughout the process of releasing a mature egg from their ovary during ovulation and helps prepare the endometrium (uterine lining) to receive the egg in the event it is fertilized by a man's sperm. However, if the mature egg goes unfertilized, levels of progesterone decrease, causing a woman to begin menstruation. If the woman does become pregnant, her placenta then begins to produce high levels of the hormone, beginning around the end of the first trimester and increasing until birth.
Progesterone tests are commonly used to determine the cause of infertility in female patients, as well as for monitoring the success of medications given to women to treat their infertility and treatments involving progesterone supplementation. They can also be utilized to determine if ovulation is occurring, to assess the possibility of miscarriage, monitor ovary and placenta functioning, and sometimes diagnose issues relating to the adrenal glands and some forms of cancer.

## PRINCIPLE

The test is based on the principle of competitive immunoassay, it uses a high sensitive anti-human progesterone monoclonal antibody and progesterone antigen, the antibody is conjugated with fluorescence latex and coated on the junction of NC membrane and sample pad, the progesterone antigen is coated on the test line. The sample applied to the test strip moves by the suction of absorbent paper, the fluorescence latex-labelled anti-human progesterone monoclonal antibody binds with the progesterone in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone. Then marked antigen-antibody complex is captured on the test line by the anti-human progesterone antigen. Meanwhile, progesterone antigen would compete with the progesterone in the sample for fluorescence latex-labelled anti-human progesterone monoclonal antibody.
Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of progesterone in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

## CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) Getein Prog test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/kit
4) SD card: 1 piece/kit
5) Sample diluent
2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein Prog test cards
User manual: 1 piece/kit
Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit
3. Sample diluent composition:
Phosphate, protein stabilizer, and surfactant.
4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labeled anti-human progesterone monoclonal antibody, the test line is coated with progesterone antigen, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.
**Note: Do not mix or interchange different batches of kits.**

## APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

## STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.
Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.
For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

## PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

## SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples***, other body fluids and samples may not get accurate results.
2. Heparin, EDTA and sodium citrate can be used as the anti-coagulant for plasma. Samples should be free of hemolysis.
3. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing.
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. SAMPLE VOLUME (***Getein1100/Getein1160/Getein1180***): ***100 μL***.

## TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Enter testing interface of Getein1100.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver ***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.
6. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card"calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use.Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver ***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.
6. Insert the test card into Getein1160/Getein1180 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 printed automatically.

For Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein 1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 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 Getein1100/Getein1160/Getein1180.
3. Make sure the test card insertion is correct and complete.

## TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.
**Others:**
Measuring range of the Progesterone test kit is 0.10 ng/mL~40.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with sample diluent, and the recommended dilution ratio is 5 times.

## 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 | 1st trimester | 135 | 4.73-50.21 |
| | 2nd trimester | 49 | 19.27-45.34 |

The upper limit of the reference interval for plasma samples is the same as the upper limit of the reference interval for serum samples.
It is recommended that each laboratory establish its own expected values for the population it serves.

## PERFORMANCE CHARACTERISTICS

Measuring Range 0.10 ng/mL~40.00 ng/mL
Lower Detection Limit ≤ 0.10 ng/mL
Within-run Precision ≤ 10%
Between-run Precision ≤ 15%

## LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferent.

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

## REFERENCES


1. J Szekeres-Bartho, JR Wilczynski, P Basta, et al. Role of progesterone and progestin therapy in threatened abortion and preterm labour. Frontiers in Bioscience J, 2008;13(5): 1981-1990.
2. G Levy , MJ Hill , C Ramirez, et al. Serum human chorionic gonadotropin levels on the day before oocyte retrieval do not correlate with oocyte maturity. Fertility & Sterility J, 2013, 99(6):1610-1614.
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 quantative 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 detail 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* | LOT | Batch code |
| | Temperature limit | IVD | *In vitro* diagnostic medical device |
| | Contains sufficient for <n> tests | EC REP | Authorized representative in the European Community/European Union |
| CE | CE mark | | Do not use if package is damaged and consult *instructions for use* |
| REF | Catalogue number | | |

Thank you for purchasing Prog Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

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