preggo

INSTRUCTIONS FOR USE

Please read this manual carefully before operation to ensure proper use.

PRODUCT NAME

PREGGO Ovulation Test Kit

PACKING SPECIFICATIONS

10/50/100 Tests per Kit

INTENDED USE

This product is used to detect the level of luteinizing hormone (LH) in women's urine to predict the time of ovulation and to guide women of childbearing age to choose the best time to conceive.

Immunochromatographic detection of luteinizing hormone levels in women's urine is a simple and rapid test technique. Luteinizing hormone (LH) is secreted by pituitary basophils. In women, luteinizing hormone cooperates with follicle-stimulating hormone to maintain the menstrual cycle of the ovary, leading to ovulation and corpus luteum formation. The production of luteinizing hormone is controlled by hypothalamic gonadotropin-releasing hormone, and is regulated by positive and negative feedback from the ovary. The peak of LH release during the menstrual cycle is closely related to ovarian ovulation. Continuous monitoring of the concentration of LH in urine samples can reveal the changes of LH in women's urine. Once the peak of gene production occurs, it indicates that the ovary is about to ovulate.

TESTING PRINCIPLE

The product adopts the principle of double antibody sandwich. When luteinizing hormone is present in the sample, the LH antigen in the sample reacts with the colloidal gold-labeled antibody (LH mAb1) on the binding pad to form a labeled antibody-antigen complex. The complex is chromatographed upward by capillary action and captured by the detection line (T line) antibody (LH mAb2) coated on a nitrocellulose membrane, and a red band appears. The complex continues to be chromatographed upwards and is captured by a control line (C line) antibody (goat anti-mouse IgG polyclonal antibody) coated on a nitrocellulose membrane, and a red band appears.

The color depth of the T line in the detection area is positively correlated with the LH content in the sample, and the LH content can be judged with the color scales of different concentrations in the colorimetric card.

MAIN COMPONENTS

1. Test pad, individually packaged in aluminum foil bag (1 piece/bag，1/5/10/25/50 piece(s)/kit)
2. Colorimetric card (1 piece/bag，1/5/10/25/50 piece(s)/kit)
3. Instruction manual (1 copy/bag，1 copy/kit)

Note: The components in different batch numbers of kits are non-interchangeable.

STORAGE CONDITIONS AND VALIDITY

Storage conditions: The original packaging should be stored in a dry place protected from light at 2~30°C, and do not freeze.

Validity period: 18 months.

The reagent should be used as soon as possible within 1 hour after unpacking the aluminum foil bag.

SAMPLE REQUIREMENTS

1. Disposable cups or clean containers should be used for urine collection. For best results, please test on the day of urine sample collection; if urine cannot be tested in time, it should be stored in a refrigerator at 2-8°C for 48 hours, or frozen at -20°C for long-term storage. Please return to room temperature before testing.
2. The best results are obtained with a urine sample taken between 10am and 8pm

daily. Never take the first urine sample in the morning.

3. Drinking a lot of water and other water intake should be avoided 2 hours before collecting urine samples to avoid affecting the detection of "LH peak" value.

TEST METHOD

1. Please first determine the menstrual cycle before testing. The algorithm is from the first day of the menstrual cycle to the first day of the next menstrual cycle as a cycle (the bleeding day is the first day). When testing, you can refer to the "Testing Schedule" to determine the "Test Start Date".

Note: Review the number of days in your menstrual cycle in the past few months. If the menstrual cycle is uncertain, use the shortest “menstrual cycle” to determine the “Test Start Date”, which should be measured continuously for at least 5 days until the “LH peak” occurs.

Testing Schedule					
Menstrual Cycle (days)	Test Start Date	Menstrual Cycle (days)	Test Start Date	Menstrual Cycle (days)	Test Start Date
21	the 6th day	28	the 11th day	35	the 18th day
22	the 6th day	29	the 12th day	36	the 19th day
23	the 7th day	30	the 13th day	37	the 20th day
24	the 7th day	31	the 14th day	38	the 21st day
25	the 8th day	32	the 15th day	39	the 22nd day
26	the 9th day	33	the 16th day	40	the 23rd day
27	the 10th day	34	the 17th day		

2. Please read the instruction manual carefully before the test, check whether the reagent is within the validity period, and check whether the kit is missing or damaged. Restore reagents and samples to room temperature before testing, and testing should be performed at room temperature.

1) Tear along the incision of the aluminum foil bag, and take out the test strip.

2) Draw urine with the small pipette and add three drops (about 75μl) to the sample hole of the test card.

3) The results can be read after 5 minutes, the results displayed after 30 minutes are invalid.

INTERPRETATION OF TEST RESULTS

1. There is no color band on the C line, indicating that this test is invalid, please take another new reagent to test again;

2. If there is a color band on the C line and a color band at the end of the T line, mark the current test result as 0 on the test chart and record the current test date.

3. C line appears a color band, and T line appears a color band. Please compare the T line color band with the color depth of the color code on the test chart, find the position with the closest color rendering depth, mark the result of the current test and record the current time test date.

4. During the detection period, test once a day for 5~10 days continuously, and draw a curve according to the [Actual Test Chart Drawing Guide].
Note: During colorimetry, if the color depth of the detection band is the same as that of two adjacent color scales, take the middle value of the two colors or take the estimated value according to how close the color is to the color scale.

LIMITATIONS OF TEST METHODS

1. The normal content of human homologous hormones TSH and FSH does not interfere with this test strip, but HCG in the urine of pregnant women will interfere with the test results of the test strip, so this test strip is not suitable for pregnant women. The result of the LH peak should be tested for pregnancy first.

2. The following conditions may affect the test results: menopause, taking hormones, steroids and birth control pills or suffering from polycystic ovary syndrome, hyperthyroidism and some endocrine diseases.

3. Suffering from primary hypogonadism, amenorrhea caused by ovarian failure, polycystic ovary syndrome, etc. can lead to abnormal increase in LH; pituitary-hypothalamic lesions, amenorrhea-galactorrhea syndrome, Kallman syndrome, psychiatric anorexia, simple LH deficiency in the pituitary gland, and delayed puberty can all lead to an abnormal decrease in LH, therefore, the test results should be judged in combination with clinical practice.

PERFORMANCE CHARACTERISTICS

1. Critical value: Testing with LH enterprise standards, the critical value of the test strip is 25 mIU/nL.

2. Specificity
2.1 Cross-reaction with Follicle Stimulating Hormone (FSH)
The detection result of FSH at a concentration of 200mIU/mL should be negative.
2.2 Cross-reaction with Thyroid Stimulating Hormone (TSH)
The detection result of TSH at a concentration of 250 μIU/mL should be negative.

3. Repeatability
Take 10 LH test strips (tests) of the same batch number, and test the LH sample solution of the same concentration. The reaction results should be consistent and the color development should be uniform.

3. Inter-batch difference
Take three batches of LH test paper and test the LH sample solution with a concentration of 25 mIU/mL. The reaction results should be consistent and the color development should be uniform.

PRECAUTIONS

1. This product is a single-use in vitro diagnostic reagent.

2. Please use it within the validity period.

3. After opening the sealed packaging bag, please use it immediately to avoid damp-induced invalidation.

4. The judgment result of this product is for reference only, and the final result should be subject to the hospital diagnosis result.

5. Certain conditions can affect the test results: pregnancy, menopause, and taking drugs such as hormones, steroids, and contraceptives.

6. Not every menstrual cycle has a peak of luteinizing hormone. If it is not detected, please test continuously or consult a professional doctor.

7. Anovulatory infertility patients have low levels of luteinizing hormone, and peak ovulation may not be detected.
8. The test results of luteinizing hormone during the menstrual cycle of patients with polycystic ovary syndrome usually do not show regular changes, and they are all weakly positive (+) or moderately positive (++).

9. The changes of luteinizing hormone during the menstrual cycle of patients with follicular luteinization are usually irregular. When luteinization of follicles is suspected, it is recommended to consult a doctor for diagnosis.

10. The urine of pregnant women contains a relatively high concentration of human chorionic gonadotropin (HCG). The subtype structure of this hormone is very similar to that of luteinizing hormone, which is prone to induce cross-reaction. Therefore, false positive results may be detected in urine samples of pregnant women.

Approval and modification date of the specification
2022.9.22

Abbreviation	Explanation	Abbreviation	Explanation
IVD	In vitro diagnostic medical device	LOT	Batch code
Σ	Contains sufficient for<n>tests		Date of manufacture
	Manufacturer		Use-by date
EC REP	Authorized representative in the European Community	30℃ 2℃	Temperature limit: 2~30℃
CE	CE Marking		Keep dry
	Do not use if package damaged		Keep away from sunlight
	Consult instructions for use		Do not re-use
REF	Catalogue number		Biological risks

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REP

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GUARANTEE AND TECHNICAL SUPPORT
If you get repeated invalid test results, or need technical support, please contact Preggo customer support.

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