LH Ovulation Rapid Test

PRODUCT NAME

LH Ovulation Rapid Test

INTENDED PURPOSE

The LH Ovulation rapid test is a rapid chromatographic immunoassay for the qualitative detection of Luteinizing Hormone (LH) in human urine, as an aid to predict ovulation time. This kit is suitable for self-testing .

Luteinizing Hormone is a glycoprotein hormone of gonadotropin. There is a small amount of luteinizing hormone (LH) in normal women, and the secretion of LH increases rapidly in the middle of menstruation, this is known as the “LH Surge”. Within 24-36 hours thereafter, it will stimulate the release of mature eggs in the ovaries, that is, ovulation. Therefore, women are most likely to become pregnant within 48 hours after the "LH Surge". Use this device to detect the level of LH in urine to predict the time of ovulation, which is used to guide women of childbearing age to choose the best period of pregnancy or to guide contraception. At present, clinically, B-ultrasound is mainly used to monitor female ovulation. Other monitoring methods include basal body temperature method, ovulation test paper method, and vaginal discharge observation method.

TEST PRINCIPLE

The test is based on the principle of double antibody sandwich method and gold immunochromatography assay. The nitrocellulose membrane is coated with LH monoclonal antibody 2 and goat anti-mouse IgG antibody, the colloidal gold conjugate pad is labeled with LH monoclonal antibody 1. During testing, when the concentration of LH in the sample to be tested is equal to or higher than the cut-off, it will react with the colloidal gold-labeled antibody to form a complex, and the reaction complex will move forward along the nitrocellulose membrane under the action of chromatography. When it reaches the test region (Test line, T), it reacts with the coated antibody to form a sandwich complex, a colored band equal to or darker than the one appearing in quality control area appears in the T line, which is a positive result. When the concentration of LH in the sample to be tested is lower than the cut-off, a colored line lighter than the one appearing in quality control area or no colored reaction line appears in the T line, which is a negative result.

No matter whether the samples contain LH or not, a colored line will always appear in the control line (C) region if the test has been performed properly.

MAIN COMPONENTS

Strip: Test strip (with desiccant packed in foil pouch), sample container and instruction for use.

Specifications / Ref No. / Components	1 Test/kit	2 Tests/kit	5 Tests/kit	10 Tests/kit	30 Tests/kit	50 Tests/kit
	A2A1S	A2B1S	A2C1S	A2D1S	A2G1S	A2I1S
Test strip	1	2	5	10	30	50
Sample container	1	2	5	10	30	50
Instruction for use	1	1	1	1	1	1

Cassette: Test cassette (with desiccant packed in foil pouch), sample container, plastic transfer pipette and instruction for use.

Specifications / Ref No. / Components	1 Test/kit	2 Tests/kit	5 Tests/kit	10 Tests/kit	25 Tests/kit	40 Tests/kit	50 Tests/kit
	A2A1C	A2B1C	A2C1C	A2D1C	A2F1C	A2H1C	A2I1C
Test cassette	1	2	5	10	25	40	50
Sample container	1	2	5	10	25	40	50
Plastic transfer pipette	1	2	5	10	25	40	50
Instruction for use	1	1	1	1	1	1	1

Midstream: Test midstream (with desiccant packed in foil pouch), sample container and instruction for use.

Specifications / Ref No. (3.0mm) / (6.0mm) / Components	1 Test/kit	2 Tests/kit	5 Tests/kit	10 Tests/kit	20 Tests/kit	25 Tests/kit
	A2A1M	A2B1M	A2C1M	A2D1M	A2E1M	A2F1M
	A2A2M	A2B2M	A2C2M	A2D2M	A2E2M	A2F2M
Test midstream	1	2	5	10	20	25
Sample container	1	2	5	10	20	25
Instruction for use	1	1	1	1	1	1

Note: 3.0 mm means the strip width is 3.0mm; 6.0 mm means the strip width is 6.0mm.

Basic components: Sample pad, gold conjugate pad, nitrocellulose membrane, absorbent paper and PVC plate. Colloidal gold conjugate pad coated with LH monoclonal antibody 1. Nitrocellulose membrane coated with LH monoclonal antibody 2 and goat anti-mouse IgG antibody.

Additional Materials Required but not Provided

Watch/timer

STORAGE AND EXPIRY

1. Store at 4-30°C in a dry place, avoid light and heat, valid for 36 months. DO NOT FREEZE.
2. The device can be transported at 4-30°C. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.
3. The product should be used within 1 hour after opening the package (Humidity: ≤60%, Temp: 10°C-30°C). Please use immediately when the humidity>60%.

SAMPLE REQUIREMENTS

1. Urine sample should be collected into clean and dry sample container, and the sample volume should be up to about 2/3 of sample container. Do not use morning urine. It is best to use urine samples at the same time (10 am to 8 pm) every day for testing. Water intake should be reduced within 2 hours before urine collection to avoid impact detection of "LH surge" value.
2. It is recommended to use fresh samples. If the sample is not tested immediately, it can be stored at room temperature for 4 hours, 2-8°C for up to 12 hours prior to testing. When the urine sample appears turbid or precipitated, do not shake it and take the supernatant for testing. Do not freeze.

TEST METHODS

Women should first determine their menstrual cycle before testing. Menstrual cycle is from the first day of this menstruation to the day before the next menstruation as a cycle (the day of bleeding is the first day). When testing, refer to the following "test schedule" to determine the "test start date", (If menstruation is irregular, take the shortest one in the last three months), generally test for 5 consecutive days.

Menstrual cycle	Test start date	Menstrual cycle	Test start date	Menstrual cycle	Test start date	Menstrual cycle	Test start date
21days	6th Day	26days	9th Day	31days	14th Day	36days	19th Day
22days	6th Day	27days	10th Day	32days	15th Day	37days	20th Day
23days	7th Day	28days	11th Day	33days	16th Day	38days	21th Day
24days	7th Day	29days	12th Day	34days	17th Day	39days	22th Day
25days	8th Day	30days	13th Day	35days	18th Day	40days	23th Day

1. Instructions must be read entirely before taking the test. Place the device at room temperature (10-30°C) for 30 minutes before use. Do not open the inner packaging until ready.
2. Test Procedure

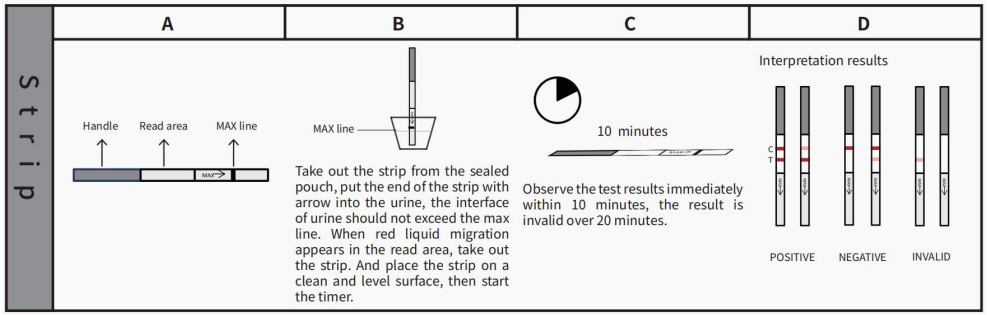
Strip: Take out the strip from the sealed pouch, put the end of the strip with arrow into the urine, the interface of urine should not exceed the max line. When red liquid migration appears in the read area, take out the strip. And place the strip on a clean and level surface, then start the timer.

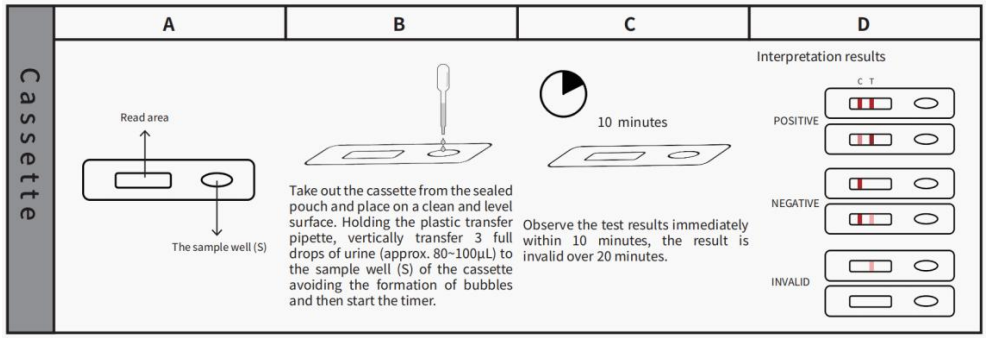
Cassette: Take out the cassette from the sealed pouch and place on a clean and level surface. Holding the plastic transfer pipette, vertically transfer 3 full drops of urine (approx. 80~100μL) to the sample well (S) of the cassette avoiding the formation of bubbles and then start the timer.

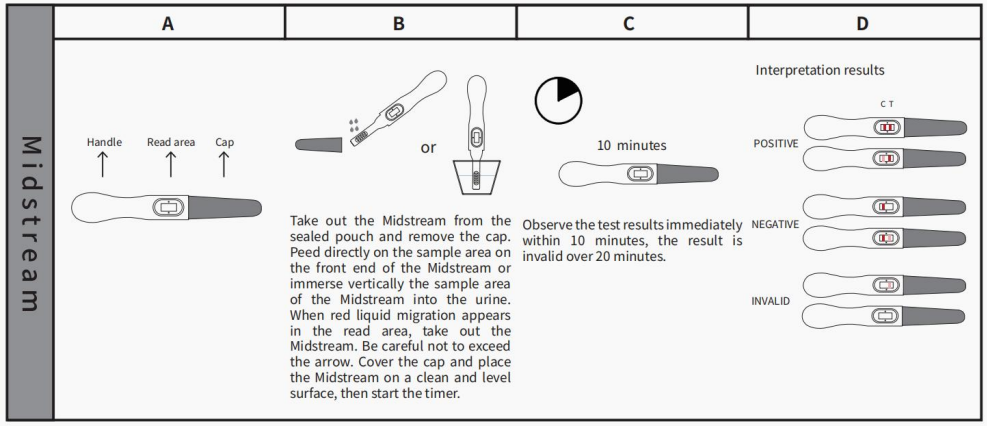
Midstream: Take out the Midstream from the sealed pouch and remove the cap. Peed directly on the sample area on the front end of the Midstream or immerse vertically the sample area of the Midstream into the urine. When red liquid migration appears in the read area, take out the Midstream. Be careful not to exceed the arrow. Cover the cap and place the Midstream on a clean and level surface, then start the timer**.**

3. Observe the test results immediately within 10 minutes, the result is invalid over 20 minutes.

The operation flow chart is as follows:

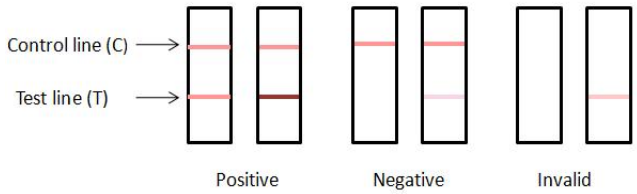






Note: The diagram is for reference only. See the real object for details. The appearance and color of the device may be different from the actual product, which has no effect on normal use.

INTERPRETATION OF RESULTS



POSITIVE: Two distinct colored lines appear and the color of testing line is stronger than or equal to the control line. It indicates that the LH surge has occurred, and ovulation is likely to occur within 24-36 hours thereafter.

NEGATIVE: One colored line appears in the control region(C). Or both colored lines appear with the color of testing line is weaker than the control line. It indicates that the LH surge has not appeared yet, and daily tests need to be continued.

INVALID: No colored lines appear or control line fails to appear, indicating the operator error or device failure.

Insufficient sample volume or incorrect procedural techniques are the most likely reasons.

Review the procedure and repeat the test with a new test device.

If the problem persists, discontinue using the kit and contact your local distributor.

LIMITATIONS

1. Concentration of LH cannot be determined by this qualitative test.
2. This detection method cannot be used for the diagnosis and screening of ovulation, nor can it be used for the detection of other luteinizing hormone related to hormone secretion disorders.
3. The normal contents of human homologous hormones TSH and FSH have no interference with this device, but HCG in the urine of pregnant women will interfere with the test results of the device, so this device is not suitable for pregnant women. If it is found that there will be a LH surge for several days, it should be tested for pregnancy first.
4. The following conditions may affect the test results: menopause, people who are taking hormones, steroids, and contraceptives, or those who have polycystic ovary syndrome, hyperthyroidism, and some endocrine diseases.
5. Suffering from primary hypogonadism, amenorrhea caused by ovarian failure, polycystic ovary syndrome, etc. can all lead to an abnormal increase in LH; pituitary-hypothalamic lesions, amenorrhea-galactorrhea syndrome, Kallman syndrome, Anorexia, pure 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 comprehensively in clinical practice.

PERFORMANCE CHARACTERISTICS

1. Test with internal references

Cut-off references: With the Cut-off references tested, C0 (blank solution): no colored lines appeared in the testing line, C1 (10mIU/mL LH): the color of the testing line is weaker than the control line, C2 (25mIU/mL LH) : the color of the testing line is equal to the control line,C3 (50mIU/mL LH): the color of the testing line is stronger than the control line.

Specific references: With the specific references which include 200mIU/mL FSH (N1) and 250μIU/mL TSH (N2) tested,the test results should all be negative.

Repeatability references: With the repetitive references (10mIU/mL LH (R1), 25mIU/mL LH (R2), 50mIU/mL LH (R3)) tested, repeated 10 times in parallel.The results and the coloration degree should be consistent.

Note: Internal control materials are prepared from WHO international standard materials.

2. Cut-off: The cut-off of the test is 25mIU/mL.

3. Clinical performance

The clinical performance of LH Ovulation Rapid Test was evaluated with 459 subjects including 60 positive and 399 negative. All the test results of LH Ovulation Rapid Test were compared with those of the reference device.

LH Ovulation Rapid Test	Reference Device		Total
	Positive	Negative	
Positive	60	0	60
Negative	0	399	399
Total	60	399	459

Diagnostic sensitivity = 100% (95%CI: 93.98%-100.00%)
Diagnostic specificity = 100% (95%CI: 99.05%-100.00%)
Total accuracy = 100% (95%CI: 99.17%-100.00%)
Explanation of terms:
Diagnostic sensitivity: True positives/all positives*100
Diagnostic specificity: True negatives/all negatives*100
Total accuracy: (True positives+true negatives)/total*100

4. Analytical specificity:

1) Interfering substances

It showed that the following substances have no effect on the test results.

Name	Concentration	Results	Name	Concentration	Results
Hemoglobin	0.8mg/mL	Negative	Acetaminophen	0.5mg/mL	Negative
Glucose	0.8mg/mL	Negative	Amoxicillin	0.5mg/mL	Negative
Albumin	80mg/mL	Negative	Aspirin	0.8mg/mL	Negative
Bilirubin	0.5mg/mL	Negative	Clomiphene Citrate	0.3μg/mL	Negative

Ascorbic acid	0.4mg/mL	Negative	Vitamin B1	0.8mg/mL	Negative

2) Cross-reactivity

It showed that there was no effect on the test results with the following substances.

Name	Concentration	Results	Name	Concentration	Results
hFSH	200mIU/mL (0mIU/mL LH)	Negative	hFSH	200mIU/mL (25mIU/mL LH)	Positive
hTSH	250μIU/mL (0mIU/mL LH)	Negative	hTSH	250μIU/mL (25mIU/mL LH)	Positive

5. Repeatability: Take the same batch of LH reagent and test the LH standards at concentrations of 10mIU/mL, 25mIU/mL and 50mIU/mL. Repeat each concentration 10 times, the reaction results and the coloration degree should be consistent.
6. Batch-to-batch variation: The results should be consistent and the coloration degree should be consistent when detecting the 25mIU/mL of LH standards by three different batches.
7. Hook effect: No hook effect was observed when testing LH samples at a concentration of 66,000 mIU/mL.

PRECAUTIONS

1. This device is only for in vitro testing of human urine.
2. This device is disposable and for in vitro diagnostic use only.
3. Check the tightness of the inner packaging before use. If there is a problem with the seal, it cannot be tested. Do not use devices beyond the expiration date.
4. The desiccant within the package is not eatable.
5. Too thin urine will lead to low specific gravity and lack of representation, so it is not advisable to drink too much water and other beverages before the test.
6. The absence of a colored line on the C line indicates that the test result is invalid, and the test must be retested with new devices.
7. The contraceptive pill will disturb the secretion of the luteinizing hormone, leading to inaccurate test results. It is recommended that women who take oral contraceptives should stop taking the drug for three months before using this device for testing.
8. When used for contraception, it is best to take contraceptive measures during intercourse when the test results show pre-ovulation , as women may sometimes ovulate early due to environmental, emotional and exertional influences.
9. When used for conception, ovulation is a complicated physiological process, and sometimes the appearance of LH surge does not necessarily result in the formation of normal corpus luteum after ovulation. If the LH surge is measured and the intercourse is normal, and you still not pregnant after 3 months, you must consult a doctor.
10. It is recommended to use the same batch number of devices for testing in the same testing cycle.
11. Wastes such as testing devices and samples after use should be considered potentially hazardous and should be properly disposed of in the same manner as an infectious agent and discarded according to local regulations.
12. This product is an in vitro diagnostic device. The final diagnosis should be made comprehensively combining various test indicators and clinical symptoms by doctors.
13. To ensure the accuracy of the test results, pay attention to the cleanliness of the collection device and the freshness and cleanliness of the urine sample when collecting urine.
14. Improper operation can also produce wrong results.
15. Any serious incident that occurs in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which you are established.
16. You should not take any decision of medical relevance without first consulting your doctor.

REFERENCES

1. Catt K. J., Dufau M. L.,Vaitukaitis J. L.. Appearance of HCG in pregnancy plasma following the initiation of implantation of the blastocyst[J]. The Journal of Clinical Endocrinology & Metabolism, 1975, 40(3): 537-540.
2. Corsan G.H., Ghazi D., Kemmann E.. Home urinary luteinizing hormone immunoassays: clinical applications[J]. Fertil Steril, 1990, 53(4): 591-601.
3. Bischof P., Bianchi P.G., Campana A.. Comparison of a rapid, quantitative and automated assay for urinary luteinizing hormone (LH), with an LH detection test, for the prediction of ovulation[J]. Hum Reprod, 1991, 6(4): 515-518.
4. Yan Zhang, Ming Zhu, Genmei Qiao, Ping Zhou, Zhijuan Zhang. The application of urine LH rapid test strip in predicting and monitoring ovulation[J]. Chinese Journal of Family Planning, 1996(1): 52-54.
5. Henry F. Vischer, Joke C.M. Granneman, Pim J. Koelink, Rute B. Marques, Jan Bogerd. Identification of a luteinizing hormone-selective determinant in the exodomain of a follicle-stimulating hormone receptor[J]. Original Research Article General and Comparative Endocrinology, 2008, 156(3): 490-498.
6. Juntao Liu, Zhuang Kong, Yang Wang, Yan Fan, Jinping Luo, Shengwei Xu, Hongyan Jin, Xinxia Cai. A rapid quantitative determination method of Luteinizing hormone with gold immunochromatographic strip[J]. Annu Int Conf IEEE Eng Med Biol Soc, 2017:17-20.

INSTRUCTIONS OF SYMBOL

	Consult instructions for use		Keep dry
30℃ 4℃	Temperature limit	LOT	Batch code
	Do not re-use	IVD	In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Use-by date	Σ	Contains sufficient for <n> tests
	Keep away from sunlight	REF	Catalogue number
EU REP	Authorized representative in the European Union		Importer
CE 0123	CE Mark, certified by TÜV SÜD		

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