No. IFU-LH-UST-01, Ver. A/5 CE0123

LH Ovulation Test (Colloidal Gold)

[Intended Use]

The LH Ovulation Test (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of Luteinizing Hormone (LH) in female urine to predict when there is a LH surge, and in turn, when you are likely to ovulate.

The LH Ovulation Test (Colloidal Gold) is designed for both self-testing and professional laboratory use, not for near patient testing.

[Model]

Cassette,LH-UST-01

[Test Principle]

Luteinizing Hormone (LH) is a kind of hormone, the content of which changes periodically with the female menstrual cycle. It effect is to stimulate the release of mature eggs within the ovaries. When its peak appears, LH abounds in the blood and urine of female. Therefore, the detection of LH in urine is a reliable criterion for the prediction of ovulation. LH Ovulation Test (Colloidal Gold) adopts the principle of chromatographic double antibody sandwich method to detect the level of LH, and is adequate for family self-test. It is helpful to improve the success ratio of pregnancy or can be used as a reference to contraception and an auxiliary diagnosis for clinical prediction of ovulation cycle.

[Warnings and Precautions]

1. For *in vitro* diagnostic use only.
2. This product is only intended for female use in ovulation testing.
3. Do not use test kit beyond the expiry date.
4. The test device should not be reused.
5. The test kit should remain in the sealed pouch until use. Do not use if the pouch is damaged or opened.
6. The used test kit can be disposed of with normal household waste in compliance with the applicable local regulations.
7. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or you are established.
8. This reagent is designed for the qualitative screening test. A confirmed diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.

[Materials and Components]

Materials provided

1) Test device
2) Dropper
3) Instruction
4) Collection container (Optional)

Materials required but not provided

1) Timer.

[Reagents]

Anti-human luteotropic hormone (LH) monoclonal antibody coated on nitrocellulose membrane, anti-mouse IgG and colloidal gold-anti-LH monoclonal antibody conjugate adsorbed on polyester membrane.

[Storage Conditions & Period of Validity]

1. Store at 4℃~30℃, and it is valid for 24 months.
2. The test kit should be kept away from direct sunlight, moisture and heat.
3. After opening the foil bag, the product should be used within 1 hour.

[Specimen Collection and Preparation]

Urine samples at any time of the day can be used for ovulation testing.

Samples should be collected in a clean, dry glass or plastic container without any special pre-treatment. If specimen cannot be assayed immediately, it can be stored at 8-30℃ for up to 4 hours prior to testing, or refrigerated at 2-8℃ for 24 hours.

[Cycle Chart]

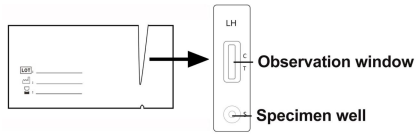
The length of the menstrual cycle is the duration from your first menstrual bleeding day to the day before the next bleeding begins. Determine the length of menstrual cycle before test. Please refer to the chart below to determine when you should start testing. If your cycle is shorter than 21 days or longer than 38 days, consult a physician. If you do not know your cycle length, you may begin the test 11 days after your first period since the average cycle length is 28 days. Perform 1 test each day over a 5 days period, or until the LH surge has been detected.

Example: If your cycle is normally twenty-six days, the Cycle Chart indicates testing should begin on day 9. The following calendar shows how to determine day 9.

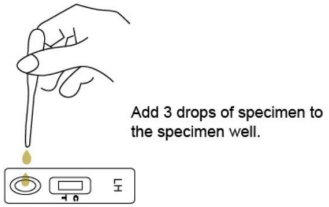
Day of Cycle				
Cycle Length			To Begin Testing	
	21	days	day	6
	22	days	day	6
	23	days	day	7
	24	days	day	7
	25	days	day	8
	26	days	day	9
Cycle Chart	27	days	day	10
	28	days	day	11
	29	days	day	12
	30	days	day	13
	31	days	day	14
	32	days	day	15
	33	days	day	16
	34	days	day	17
	35	days	day	18
	36	days	day	19
	37	days	day	20
	38	days	day	21
	39	days	day	22
	40	days	day	23

[Test Procedure]

Allow the test device and the specimen to equilibrate to room temperature (15- 30 °C) prior to testing.

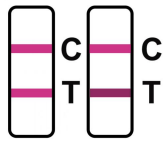


1. To begin testing, open the sealed pouch by tearing along the notch. Remove the test device from the pouch and use it as soon as possible.

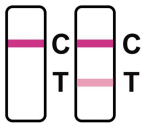


2. Lay the device flat on table. Pinch the bulb at the upper end of the dropper, place the lower end in the urine, and then slowly loosen the bulb. Hold the dropper vertically to add 3 full drops of urine to specimen well "S".
3. Wait for red line(s) to appear. The test results should be read in approximately 3-10 minutes. Do not interpret results after 10 minutes.

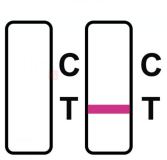
[Interpretation of test results]



Positive (LH Surge): If two red lines are visible, and the test line (line T) is equal to or darker than the control line (line C), one will probably ovulate in the next 24-48 hours. If trying to get pregnant, the best time to have intercourse is after 24 but before 48 hours.



Negative (No LH Surge): Only one red line appears on the control region (C), or the test line (line T) appears but is lighter than the control line (line C). This means there is no LH surge.



Invalid: No coloured line appears in the control region (C). Repeat with a new test kit. If test still fails, please discontinue using the test kit immediately and contact the distributor or the store where you bought the product, with the lot number.

[Quality Control]

A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume.

[Limitations of inspection methods]

1. This test may not be used as a form of birth control.
2. Concentration of LH cannot be determined by this qualitative test.
3. This reagent is designed for the qualitative screening test. A confirmed diagnosis should be made by other methods.
4. For human urine only. False results may occur when the test is taken in a wrong way.

[Performance Characteristics]

Limit of detection

The limit of detection of the LH Ovulation Test (Colloidal Gold) is 25 mIU/ml.

Specificity

The hFSH (200 mIU/mL), hTSH (200 μIU/mL), hematuresis (Hb concentration of 1.8 g/L), bilirubinuria (85 μmol/L), proteinuria (5.65 mmol/L), Ascorbic Acid (0.2 mg/mL), caffeine (0.2 mg/mL), glucose (20 mg/mL), urine specific gravity (1.008~1.030) and urine pH (3.0~9.0) did not affect the test results of the LH Ovulation Test (Colloidal Gold).

Repeatability

Samples of different concentrations of LH standards were tested separately using the same lot of kit, each concentration was tested 10 times. All test results of 50 mIU/ml, and 25 mIU/ml of LH standards is positive, and all test results of 12.5 mIU/ml of LH standards is negative.

Hook effect

There was no hook effect when the concentration of LH is up to 2000 mIU/mL.

HAMA (human anti-mouse antibody) interference

20 ng/mL HAMA has no effect on the detection results of the test device.

Diagnostic specificity and sensitivity

A clinical evaluation was carried out on 100 clinical samples from women of childbearing age, compared the results obtained using the LH Ovulation Test (Colloidal Gold) with a commercially available Ovulation Test.

Clinical Accuracy of LH Ovulation Test (Colloidal Gold):

DEEPBLUE LH Test	Reference		Total
	Positive (+)	Negative (-)	
Positive (+)	47	0	47
Negative (-)	0	53	53
Total	47	53	100

Positive agreement (Sensitivity):>99.9%
Negative agreement (Specificity) : >99.9%
Total consistency rate (Accuracy):>99.9%

[References]

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• Dos Santos EC, Lalonde-Larue A, Antoniazzi AQ, Barreta MH, Price CA, Dias Gonçalves PB, Portela VM, Zamberlam G. YAP signaling in preovulatory granulosa cells is critical for the functioning of the EGF network during ovulation. Mol Cell Endocrinol. 2022 Feb 5;541:111524. doi: 10.1016/j.mce.2021.111524. Epub 2021 Nov 29. PMID: 34856345.

• Richards JS, Russell DL, Ochsner S, Hsieh M, Doyle KH, Falender AE, Lo YK, Sharma SC. Novel signaling pathways that control ovarian follicular development, ovulation, and luteinization. Recent Prog Horm Res. 2002;57:195-220. doi: 10.1210/rp.57.1.195. PMID: 12017544.

• Rijken-Zijlstra TM, Haadsma ML, Hammer C, Burgerhof JG, Pelinck MJ, Simons AH, van Echten-Arends J, Arts JG, Land JA, Groen H, Hoek A. Effectiveness of indometacin to prevent ovulation in modified natural-cycle IVF: a randomized controlled trial. Reprod Biomed Online. 2013 Sep;27(3):297-304. doi: 10.1016/j.rbmo.2013.05.009. Epub 2013 May 22. PMID: 23876971.

[Instruction of Symbols]

CE 0123	CE Marking with NB Identification	LOT	Batch number
	Consult instructions for use	IVD	*In vitro* diagnostic medical device
	Do not re-use		Date of manufacture
30°C 4°C	Storage temperature	Σ	Contains sufficient for <n> tests
	Manufacturer		Use before the date
EC REP	Authorized Representative in European Community		Keep dry
	Keep away from sunlight		Do not use if package is damaged and consult instructions for use

REF	Catalogue number	UDI	Unique device identifier

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EC REP
Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

Specification	REF
1 pc/box	LH1UST-1
2 pcs/box	LH1UST-2
3 pcs/box	LH1UST-3
5 pcs/box	LH1UST-5
10 pcs/box	LH1UST-10
20 pcs/box	LH1UST-20
25 pcs/box	LH1UST-25
40 pcs/box	LH1UST-40
50 pcs/box	LH1UST-50
100 pcs/box	LH1UST-100

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