LH Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

Please read the instruction for use carefully before performing the test or use after consulting your doctor.

CE IVD REF

In Vitro Diagnosis

For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

The LH Rapid Test Cassette (Colloidal Gold) is a one step immunochromatographic assay designed for in vitro qualitative determination of human luteinizing hormone (hLH) in urine strip to predict time of ovulation for both the professional and self-testing.

Since current study shows that 38 % of women have the length of the LH surge only lasting less than 10 hours, we recommend you use Ovulation Test twice a day in the morning and the evening, to more effectively and accurately catch your ovulation timing. The Ovulation Test can help you predict the two most fertile days following the detected LH surge. Having intercourse within these days will maximize your chances of becoming pregnant.

SUMMARY AND EXPLANATION

Human luteinizing hormone (hLH) is a glycoprotein hormone secreted by the anterior pituitary. This hormone has a molecular weight of approximately 30,000 and is composed of alpha and beta subunits. The amino acid sequence of alpha-hLH is essentially identical to that of other hormones including follicle stimulating hormone (FSH), thyroid stimulating hormone (TSH) and human chorionic gonadotropin (hCG). It is the beta subunit of hLH that confers the biological and immunochemical specificity of the hormone (1). LH and FSH together with other steroid hormones are known to play important roles in regulating the ovulation and ovarian functions during the menstrual cycle. Maturation of an ovarian follicle and its oocyte begins during the end of the preceding menstrual cycle. In response to FSH released by the pituitary, the follicle undergoes rapid growth. As follicles develop, estradiol secretion begins to rise slowly and is followed by a rapid increase. This increase of estradiol level is generally believed as the trigger for the rapid rise and peaking of LH activity at the mid-cycle (LH surge). Approximately 12-24 hours after the LH surge, the wall of the enlarged follicle ruptures at ovulation and the mature ovum is extruded. After ovulation, LH returns to its base line level within two days with the concomitant increase of progesterone level to initiate luteal phase. The luteal phase lasts predictably about 14 days. The onset of the hLH surge precedes ovulation by approximately 30 hours The analysis of hLH has been used successfully to time oocyte retrieval for in vitro fertilization. and would similarly assist timing of artificial insemination.

PRINCIPLE

The LH Rapid Test Cassette (Colloidal Gold) is a qualitative sandwich immunoassay for the determination of human Luteinizing hormone (hLH) in urine. The membrane was pre-coated with goat anti-hLH on the test line area and goat anti-mouse on the control line area. During the test, the sample urine is allowed to react with a colored conjugate (mouse anti-hLH monoclonal antibody-colloid gold conjugate) which was pre-dried on the test Strip. The mixture then moves upward on the membrane chromatographically by a capillary action. When hLH is present in the sample, a color band with a specific anti-hLH-colored conjugate complex will form on the membrane. A light color line will always appear at the control region. This control line serves as a reference of the color intensity of approximately 25mIU/mL LH. When the intensity of test line is higher than that of control line the test is positive, indication the LH surge is likely in process.

SPECIFICATIONS AND MATERIAL PROVIDED:

Test devices. Each strip is packed in a foil pouch with a disposable dropper and a package of desiccant.

Instruction for use.

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

Sample container and disposable gloves

No other equipment or reagents are needed

STORAGE AND STABILITY

The test kit can be stored at room temperature (2℃-30℃) in the sealed pouch to the date of expiration.

The test kits should be kept away from direct sunlight, moisture and heat.

Do not freeze.

The stability of the kit under these storage conditions is 24 months.

PRECAUTIONS

1. FOR IN-VITRO DIAGNOSTIC USE ONLY (IVD), NOT for internal use.
2. Read directions for use carefully before performing this test. Perform each step exactly as described.
3. Do not use beyond the expiration date marked on the foil pouch.
4. Each Ovulation Test can only be used once; do not re-use the Ovulation Test
5. Do not use the Test if the foil pouch is damaged.
6. Once the foil pouch has been opened, the Test should be used immediately.
7. Discard each Ovulation Test after use. Treat urine samples and used test devices as if they were potentially infectious. Avoid contact with skin.
8. When uses this product ， you should not take the hCG or the LH medicine which may influence the test result, moreover, In pregnancy, menopause or use of contraceptives during the test ， the result will not normal.
9. KEEP OUT OF REACH OF CHILDREN.

WHEN TO MAKE THE TEST

Determine the Length of Your Menstrual Cycle

Your Menstrual Cycle Length is the number of days from the first day of your period (menstrual bleeding) to the last day before your next period starts. Think back over the last few months to decide what your usual cycle length has been.

Circle your usual cycle length on the WHEN TO START CHART below. Select the number directly underneath. Starting the first day of your last period, count ahead the selected number of days on your calendar. This is the day you should begin testing. Compare the results of the test after continuous testing for 5 days or the maximum of LH appears, and find out LH surge level. To forecast the ovulation period, If the menstrual cycle is less than 21 days or more than 38 days, one should take tests according to the physicians.

WHEN TO START CHART

Circle Your Usual Cycle Length

21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	
38	39	40															
06	06	07	07	08	09	10	11	12	13	14	15	16	17	18	19	20	
21	22	23															

Count ahead this many days STARTING WITH THE FIRST DAY of your LAST period.

Note: If you are unsure about your cycle length, you may want to use your shortest cycle length when reading the chart. If you do this, you may need to test for more than 5 days.

“When to Start Chart” shows that I will count ahead 11 days beginning with the seventh. When I count 11 days ahead on the calendar, I find that I will collect and test my urine starting on the 17th ”. (See “Specimen Calendar ” below).

Specimen Calendar

Sun.	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.
	1	2	3	4	5	6
(7)	8	9	10	11	12	13
14	15	16	<17>	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

( )--First day of your last period

< >--Begin testing with the Ovulation Test Strip (Urine).

Menstrual Cycle	Beginning Time of Testing
21-22 days	The 6th day
23-24 days	The 7th day
25 days	The 8th day
26 days	The 9th day
27 days	The 10th day
28 days	The 11th day
29 days	The 12th day
30 days	The 13th day
31 days	The 14th day
32 days	The 15th day
33 days	The 16th day
34 days	The 17th day
35 days	The 18th day
36 days	The 19th day
37 days	The 20th day
38 days	The 21st day

TEST PROCEDURE

1. SAMPLE COLLECTION AND HANDLING

The Ovulation Test is formulated for use with fresh urine specimens. The test should be used right after the specimen collection. The urine does not require any special pretreatment. Choose a convenient time of the day to perform the test, wear gloves to collect the urine sample into a clean and dry container. Try to test at about the same time each day for the entire cycle.

For best results, test between 10:00 am and 8:00 pm.

Test Strip together with patients’ samples, controls or reference materials should be brought to room temperature prior to testing.

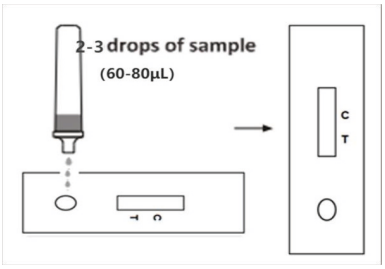
DIRECTIONS FOR USE

1.Bring the sealed pouch to room temperature. Remove the Strip from the foil pouch.

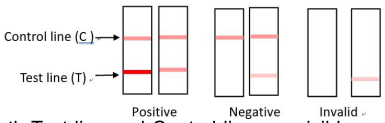
2.add 2-3 full drops (60-80uL) of urine by the disposable plastic straws vertically to the sample well (S) of the cassette. Avoid the formation of bubbles and then start the timer.. As the test begins to work, you may notice a light burgundy flow moving across the Test and Control windows.

3.Read the result within 10 minutes, DO NOT INTERPRET RESULT AFTER

15 minutes. Dispose the test device after a single use.
Note: Depending on the concentration of LH in the urine sample, Wait the full ten minutes to confirm the result. Do not read the one step LH Test after 15 minutes as this may give an incorrect test result. This is a single use test. Please safely dispose of the Strip, regard this as infectious material and dispose of the test appropriately after use.



INTERPRETATION OF THE RESULTS



POSITIVE: If both Test line and Control line are visible and the test band is more intense than or equal to the control (C) band, the test result is positive, which means the ovulation is likely to occur in the next 24-48 hours.
NEGATIVE: One burgundy line is visible in the control area(C); no band is found in the Test area (T), or the color of the Test(T) band is less intense than that of the control(C) one. The result is negative, indicating basal LH level of the tested specimen.
INVALID RESULT: If there is no distinct burgundy colored band visible both in the Test(T) and Control (C) area, the test is invalid, Retest the specimen with a new device.
Invalid might be resulted from,

- The absorbent tip not being wetted thoroughly.
- Reading the test result too early or too late. A 10 minutes reaction time is required.

For further information, see LIMITATIONS OF THE PROCEDURE.

Q&A

1. Can I use the Test to avoid pregnancy?
No, the test shouldn't be used as a form of birth control.
2. Do alcohol or common medications affect the test?
No, but you should consult your physician if you are taking any medication.
3. Once I see a positive result, when is the best time to have intercourse?
Ovulation is likely to occur within 24-48 hours. This is your most fertile time. Sexual intercourse within this time frame is advised.
4. I have received a positive result and had intercourse during these fertile days. I have not become pregnant. What shall I do?
There are many factors that can affect your ability to become pregnant. Often you may need to use the test kit for 3-4 months before achieving pregnancy. You and your partner should consult your physician if pregnancy is not achieved after 3-4 months.

QUALITY CONTROL

Built in Quality Control Features:
The appearance of a line in the control area indicates that the LH Rapid Test Cassette (Colloidal Gold) is performing properly and serves as a procedural control. It is recommended that a positive hLH control (containing 25-50mIU/mL hLH) and a negative hLH control (containing 0mIU/mL hLH) are evaluated to verify proper test performance when a new shipment of tests is received.

PERFORMANCE CHARACTERISTICS

1. CUT-OFF
LH Rapid Test Cassette (Colloidal Gold) will display positive results with specimens containing hLH at levels of 25mIU/ml or greater.
2. ACCURACY
Comparison studies on the LH Rapid Test Cassette (Colloidal Gold) with a legally marketed device were performed in-house and in a clinical reference laboratory. Positive and negative results were compared and the correlation was ＞99%.
3. SPECIFICITY
The following compounds exhibited no interference when dissolved in urine, which had hLH levels of 0 and 50 mIU/ml.

hCG……100mIU/ml
hFSH……200mIU/ml
hTSH……100μIU/ml

Acetaminophen	20mg/dl
Acetosalicylic Acid	20mg/dl
Ascorbic Acid	20mg/dl
Atropine	20mg/dl
Caffeine	20mg/dl
Gentisic Acid	20mg/dl
Glucose	100mg/dl
Hemoglobin	10mg/dl
Ampicillin	20mg/dl
Tetracycline	20mg/dl

LIMITATION OF THE PROCEDURE
The test works only when the test procedures are precisely followed.
This test may not be used as a form of birth control.
Consult a doctor if irregular or unusually long cycles are experienced.
1. LH is normally detectable at low levels in urine or serum of healthy men (2-15 mIU/mL), or premenopausal women not during the LH surge. Prior to the tests the following charts should be consulted.

	LH level (mIU/mL)
Postmenopausal Women	10-200
Premenopausal Women	
a. baseline level	5-20
b. surge level	40-200
Men	5-15

Each laboratory should establish their own criteria for interpretation of results as baseline hLH levels and patterns of LH secretion can vary among individuals.
When baseline LH level of a patient is in doubt, a urine sample collected 7 days after the beginning of the menstrual cycle can be used as the negative reference. If a sample produced more intense surge band than the day 7 sample, a LH surge is indicated.
2. Women suffering from polycystic ovary syndrome may have elevated LH concentration.
3. Reagents used in the test kit are cross-reactive with hCG. The kit is intended only for the analysis of hLH in hCG-free samples. Pregnant woman should not use this test, since urine of pregnant women contains high concentration hCG , there will be false positive result.
4. As is true with any diagnostic procedure, the user should evaluate data obtained by the use of this kit in light of other clinical information and consult to the physicians for the final diagnosis of ovulation before any decision of medical relevance.

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Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃-30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:
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