

# LH Ovulation Test (Strip)

For self-testing and in vitro diagnostic use only

CE 0197

Core tests®

## INTENDED USE

LH Ovulation Test is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to predict the time of ovulation.

## SUMMARY

Ovulation is the release of an egg from the ovary. The egg passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH). This is known as the "LH Surge" and usually takes place in the middle of the menstrual cycle. LH triggers the release of an egg from the ovary.

LH Ovulation Test is a complete system to help predict the time of ovulation and peak fertility. It is during this fertile time that pregnancy is most likely to occur.

The LH Ovulation Test detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24-48 hours.

## PRINCIPLE

The LH Ovulation Test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of LH in urine. The membrane is pre-coated with anti- $\alpha$  LH capture antibody on the test line region and goat anti-mouse on the control line region. During testing, the urine specimen is allowed to react with the colored conjugate (mouse anti- $\beta$  LH monoclonal antibody-colloidal gold conjugate) which has been pre-dried on the test strip. The mixture then moves upward on the membrane chromatographically by capillary action. For a positive result, a pink-colored line with the specific antibody-LH-colored conjugate complex will form in the test line region of the membrane, and the color intensity of the test line is as the same as, or stronger than that of the control line. This means a positive result. For a negative result, the color intensity of the test line is weaker than that of the control line. The test result means that the concentration of LH in the urine specimen is in the normal level. Regardless of the presence of LH, as the mixture continues to move across the membrane to the immobilized goat anti-mouse, a pink-colored line at the control line region will always appear. The presence of this pink-colored line serves as: 1) verification that sufficient volume is added, 2) that proper flow is obtained, and 3) as a control for the reagents.

## COMPOSITION

The test strip contains anti- $\beta$  LH on colloidal gold particles and a combination of anti- $\alpha$  LH coated on the membrane.

## WARNINGS AND PRECAUTIONS

1. Read the instruction carefully before performing this test.
2. Do not use beyond the labeled expiration date.
3. The test strip should remain in the sealed pouch until use. Do not use if the pouch is damaged or opened.
4. Do not reuse the test strip. Discard it in the dustbin after single use.
5. Do not touch the membrane located within the windows.
6. Do not swallow the desiccant.

## STORAGE

The test strip should be stored at 2-30°C in the sealed pouch for the duration of the shelf life. Do the test in 1 hour when you open the pouch. DO NOT FREEZE.

## SAMPLE COLLECTION

1. Urine specimen must be collected in a clean, dry container,

either plastic or glass, without preservative. For the best result, collect your urine at about the same time each day, for example, between 10:00AM and 8:00PM. Do not collect your first urine after waking up.

2. Specimens may be refrigerated (2°C to 8°C) and stored up to 72 hours prior to assaying. If specimens are refrigerated, they must be equilibrated to room temperature before testing.

## WHEN TO START TESTING

1. Determine the Length of Your Menstrual Cycle.
2. Your Menstrual Cycle Length is the number of days from the first day of your period (menstrual bleeding) to last day before your next period starts. Think back over the last few months to decide what your usual cycle length has been.
3. Circle your usual cycle length on the WHEN TO START CHART right. Select the number directly underneath.
4. 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.

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

Circle Your Usual Cycle Length WHEN TO START CHART	
YOUR CYCLE LENGTH	START TO TEST ON
21 days	day 6
22 days	day 6
23 days	day 7
24 days	day 7
25 days	day 8
26 days	day 9
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
more than 40 days	consult a doctor

## TEST PROCEDURE

Allow the test strip, urine specimens and/or controls to equilibrate to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.



1. Remove the test strip from the sealed pouch and use it as soon as possible.
2. Immerse the test strip in the urine specimen for at least 5 seconds with the arrow end pointing toward the urine. Do not immerse the strip above the printed MAX line.
3. Take the strip out and lay the strip flat. Or leave the test strip in the urine specimen as long as the strip is not immersed above the MAX line.
4. Wait for pink-colored lines to appear. Read result between 3-8 minutes. Do not read result after 10 minutes.

## INTERPRETATION OF RESULTS

### LH Surge:

If two pink-colored lines are visible and the test line (T) is equal to or darker than the control line (C), you will probably ovulate in the next 24-48 hours. If you want to be pregnant, the best time to have intercourse is after 24 hours but before 48 hours.

### No LH Surge:

Only control line (C) appears or the test line (T) is present but lighter in color intensity than the control line. This indicates that no LH surge has been detected and you should continue daily testing.

### Invalid:

No line appears in the control region.

NOTE: Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test strip. If the problem persists, please contact your local distributor.

## QUALITY CONTROL

A procedural control is included in the test. A colored line appearing on the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive reagents. A clear background in the membrane is considered an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will be clear to give a discernible result.

## EXPECTED VALUES

LH is contained in the serum and urine of healthy men, the common level is 2-15mIU/mL. The ranges of concentration are as below:

Kind of people	Range(mIU/mL)
Women after menopause	10-200
Women in bearing age	Base level: 5-20
	Fastigium: 40-200
Men	2-15

Because there are some individual differences existing between the time of base level and fastigium, the test on the 7th day of menstrual cycle can be made as the reference of base level.

## PERFORMANCE CHARACTERISTICS

Analytical Sensitivity: No less than 25mIU/ml

Analytical Specificity: The test results show negative for the 200 mIU/ml hFSH and 1000 $\mu$ IU/ml hTSH specimens.

Diagnostic Sensitivity and Diagnostic Specificity: This LH Ovulation Test has been designed to produce a definitive colored line at test region when tested with 25mIU/ml or higher of LH (WHO 4th IS for human luteinizing hormone) at room temperature. 900 known negative urine specimens were equally divided into 6 groups. Each group of specimens (150) were spiked with LH to the concentration of 0mIU/ml, 5mIU/ml, 15mIU/ml, 25mIU/ml, 50mIU/ml and 5IU/ml separately. Each group of specimen was tested with LH Ovulation Test. The results from this study gave >99% agreement with the expected results.

Result	0mIU/ml	5mIU/ml	15mIU/ml	25mIU/ml	50mIU/ml	5IU/ml	Total
Positive	0	0	0	150	150	150	450
Negative	150	150	150	0	0	0	450
Total	150	150	150	150	150	150	900

Diagnostic sensitivity=100% (450/450)

Diagnostic specificity=100% (450/450)

Interference Testing: The following substances were added in LH free and LH spiked urine specimens. None of the substances at concentration tested interfered in the assay.

For example:

Acetaminophen	0.2mg/ml	Caffeine	0.2mg/ml
Acetylsalicylic Acid	0.2mg/ml	Gentisic Acid	0.2mg/ml
Ascorbic Acid	0.2mg/ml	Glucose	20mg/ml
Atropine	0.2mg/ml	Hemoglobin	10 $\mu$ g/ml

## LIMITATION

1. Reagents used in the test strip are cross-reactive with HCG. The strip is intended only for the analysis of LH in HCG-free specimens.
2. Women suffering from polycystic ovary syndrome may have elevated LH concentration.
3. The test strip will not work properly if you are pregnant, menopausal, or taking birth control pills.
4. The test results should not be affected by pain relievers. Antibiotics containing HCG or LH may affect the test and

should not be taken while using the LH ovulation test.

5. The test provides a presumptive diagnosis for the time of ovulation. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.

## QUESTIONS & ANSWERS

1. Q: Can I use this LH Ovulation Test to avoid pregnancy?  
A: No, the test should not be used as a form of birth control.
2. Q: Do alcohol or common medications affect the test?  
A: No, but you should consult your physician if you are taking any hormonal medication. Also, recent oral contraceptive use, breast feeding, or pregnancy could affect the test results.
3. Q: Why should I not use first morning urine? What time of the day should I perform the test?  
A: We do not recommend first morning urine because it is concentrated and may give a false positive result. Any other time of day is suitable. For best results, try to collect your urine at approximately the same time each day.
4. Q: Will the amount of liquid I drink affect the result?  
A: Heavy intake of fluids prior to testing will dilute the hormone in your urine. We suggest that you limit your fluid intake for about two hours before you perform the test.
5. Q: Once I see a positive result, when is the best time to have intercourse if I want to get pregnant?  
A: Once you see a positive result, your ovulation is likely to occur within 24-48 hours. This is your most fertile time. Sexual intercourse after 24 hours but before 48 hours is advised.

## REFERENCES

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2. Winter G, Griffiths AD, Hawkins RE, et al. Making antibodies by phage display technology. Annu Rev Immunol, 1994, 12: 433-455.
3. Richard L. Stouffer. Structure, Function, and Regulation of the Corpus Luteum. Knobil and Neill's Physiology of Reproduction (Third Edition), 2006, Pages 475-526.
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## Index of Symbols

	Do not reuse		Use by		Lot Number
	Manufacturer		Temperature Limitation		CE Mark
	For In Vitro Diagnostic Use		Consult instructions for use		
	Contains sufficient for <-> tests		Authorized Representative		

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