

# LH Ovulation Test (Strip)

CE 0197



For self-testing and in vitro diagnostic use

## 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 24-36 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-beta LH capture antibody on the test band region and goat anti-mouse on the control band region. During testing, the urine specimen is allowed to react with the colored conjugate (mouse anti-alpha 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 band with the specific antibody-LH-colored conjugate complex will form in the test band 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 the positive results. 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 sample 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 band at the control band region will always appear. The presence of this pink-colored band serves as: 1) verification that sufficient volume is added, 2) That proper flow is obtained, and 3) as a control for the reagents.

## PRECAUTIONS

1. Read instruction for use carefully before performing this test.
2. Do not use the test kit beyond the expiration date.
3. The test strip should remain in the sealed pouch until use.
4. Do not reuse the strip. Discard it in the dustbin after use.
5. Treat urine specimen and used strip as if they are potentially infectious.

## REAGENTS

Each test contains an anti-LH capture antibody coated membrane and colloidal gold particles coated with mouse anti-LH monoclonal antibody.

## STORAGE AND STABILITY

The test device can be stored at 2-30°C in the sealed pouch. The test device is stable through the expiration date printed on the sealed pouch. DO NOT FREEZE.

## SPECIMEN COLLECTION

1. Collect urine at about the same time each day. Use a clean, dry container, for example, glass or plastic cup each time.
2. Do not use first morning urine samples as LH is synthesized in your body early in the morning. It will not show up in your urine until later in the day.
3. The best time to collect your urine is between 10am-8pm.
4. Reduce liquid intake about 2 hours before collecting your urine as a diluted urine sample can prevent the test from detecting LH surge.
5. Testing should be performed immediately after the specimens have

been collected. Do not leave the specimens at room temperature for prolonged periods.

## MATERIALS

### Materials Provided

Each test strip is individually sealed in a foil pouch.

1. One LH Ovulation Test Strip
2. Instruction

### Materials required but not supplied

1. Timer
2. Specimen container

## WHEN TO START TESTING

To determine when to start testing, you must first determine the length of your Menstrual Cycle.

Your menstrual cycle length is the number of days from the first day of your period to the last day before your next period starts. Determine the usual length of the menstrual cycle over the last few months. Then, refer to the Cycle Chart to determine on which day you should begin testing.

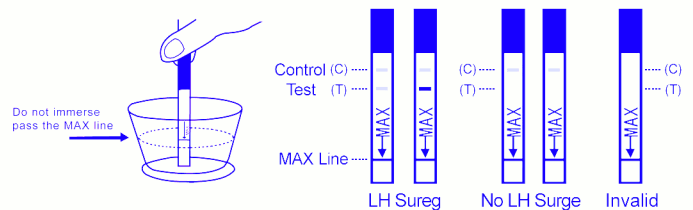
NOTE: If you are unsure about your cycle length, you may begin the test 11 days after your first period, since the average cycle length is 28 days. Perform 1 test each day over a 5 day period or until the LH surge has been detected.

## TEST PROCEDURE

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

## CYCLE CHART

Your cycle Length	Start to test on
21days	days5
22days	days6
23days	days7
24days	days7
25days	days8
26days	days9
27days	days10
28days	days11
29days	days12
30days	days13
31days	days14
32days	days15
33days	days16
34days	days17
35days	days18
36days	days19
37days	days20
38days	days21
39days	days22
40days	days23



1. Remove the test strip from the sealed pouch and use it as soon as possible.
2. Immerse the test strip in the urine sample for at least 5 seconds with the arrow end pointing toward the urine. Do not immerse the strip above the printed MAX line.
3. Remove the test strip from the urine and lay flat on a non-absorbent clean surface. 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 within 10 minutes. Do not read result after 15 minutes.

## INTERPRETATION OF RESULTS

### LH Surge:

If two pink-color lines are visible and the test line (T) is equal or darker than the control line (C), one 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 clear to give a discernible result.

## EXPECTED VALUES

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

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

- Because there are some individual difference exists between the time of base level and fastigium, so the test on the 7th of menstruate period can be made as the reference of base level.

## LIMITATION

- Antibiotics containing HCG or LH may affect the test and should not be taken while using the LH Ovulation Test.
- The level of LH is usually high in the women with polycystic ovarian syndrome.
- For women who are pregnant, menopausal or taking birth control pills, the test will not work properly.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

## PERFORMANCE CHARACTERISTICS

### Sensitivity & Specificity

- The LH Ovulation Test detects urinary LH concentrations equal to or greater than 20mIU/mL (with WHO 2nd IS as standard) as indicated by the development of a dark pink-colored line in the test region.

500 LH tests were tested by urines spiked with LH to the concentration of 0mIU/mL, 10mIU/mL, 20mIU/mL, 25mIU/mL and 30mIU/mL. The samples containing LH higher than 20mIU/mL all produce positive results.

Table-1

LH Conc. Result	0 mIU/mL	10mIU/mL	20mIU/mL	25mIU/mL	30mIU/mL
Negative	100	100	0	0	0
Positive	0	0	100	100	100
Invalid	0	0	0	0	0
Total	100	100	100	100	100

400 known negative urine samples were equally divided into 4 groups. Each group of samples (100) were spiked with LH to the concentration of 0mIU/mL, 25mIU/mL, 50 mIU/mL and 5IU/mL separately, calibration against WHO 3<sup>rd</sup> international standard. Each group of samples were tested with CORE LH test strips. The results from this study gave 100% agreement with the expected results.

Table-2

Result	0mIU/mL	25mIU/mL	50mIU/mL	5IU/mL	Total
Positive	0	100	100	100	300
Negative	100	0	0	0	100
Total	100	100	100	100	400

Diagnostic sensitivity= 100% (300/300)

Diagnostic specificity= 100% (100/100)

## Interference Test









- The following substances were added to LH-free and 300mIU/mL LH-spiked urine samples. At the concentrations tested, none of the substances interfered in the assay.

Acetaminophen	20mg/dl	Glucose Acid	2g/dl
Acetylsalicylic Acid	20mg/dl	Hemoglobin	1mg/dl
Ascorbic Acid	20mg/dl	Caffeine	20mg/dl
Atropine	20mg/dl		

## QUESTIONS & ANSWERS

- 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.
- 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.
- 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.
- 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.
- 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.
- Q: I received a positive result and had intercourse during these fertile days, but why I didn't get pregnant?  
A: There are so many factors that can affect your ability to become pregnant. It often takes normal, healthy couples many months to achieve pregnancy. If you do not get pregnant in the first month, please continue to use the test kit before achieving pregnancy. If pregnancy is not achieved after 3-4 months, you and your partner should consult your physician.

## INDEX OF SYMBOLS

	Consult Instructions for use		DO NOT REUSE		MANUFACTURER
	For In Vitro Diagnostic Use		USE BY		EUROPEAN REPRESENTATIVE
	TEMPERATURE LIMITATION		LOT NUMBER		

## REFERENCES

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Core Technology Co., Ltd.  
Room 100, C Building, No.29 Life Park Rd.,  
Changping District, Beijing, 102206 China



Wellkang Ltd t/a Wellkang Tech Consulting  
Suite B, 29 Harley Street  
LONDON W1G 9QR  
England, United Kingdom

KR6080714

Version 1.0

Effective Date: 2008-08-08