

ALL TEST™ LH Ovulation Rapid Test Cassette (Urine)

Package Insert

For Self-testing

REF FLH-102H English

【INTENDED USE】

The LH Ovulation Rapid Test Cassette (Urine) is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation.

【SUMMARY】

Ovulation is the release of an egg from the ovary. The egg then 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) which triggers the release of a ripened egg from the ovary. This "LH surge" usually takes place in the middle of the menstrual cycle. The LH Ovulation Rapid Test Cassette (Urine) 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 Rapid Test Cassette (Urine) detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24-36 hours. The test utilizes a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH. Important: The LH surge and ovulation may not occur in all menstrual cycles.

【PRINCIPLE】

Ovulation is the release of an egg from the ovary. The egg then 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) which triggers the release of a ripened egg from the ovary. This is known as an "LH surge", and usually takes place in the middle of the menstrual cycle. It is during this fertile time that pregnancy is most likely to occur. It is important to note that an LH surge and ovulation may not occur in all cycles.

The LH Ovulation Test is a rapid lateral flow immunoassay for the qualitative detection of LH surges in urine, signaling that ovulation is likely to occur in the next 24-36 hours. The test utilizes a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH.

【SPECIMEN COLLECTION AND PREPARATION】

- Determine the optimal time for urine collection. For best results, collect urine at about the same time each day. Some women have found that their best specimen is after 12 noon. Do not collect the first urine specimen after waking up.
- Reduce liquid intake approximately 2 hours prior to urine collection.
- Record the date, cycle day and time of urine collection. See the TEST RESULTS CHART at the end of this package insert.
- Urine can be stored at room temperature for up to 8 hours or at 2-8°C for up to 24 hours. Do not freeze. For best results, test urine on the same day that it is collected. If refrigerated, let urine reach room temperature before testing. Do not shake the container. If a sediment forms at the bottom of the collection container, allow the sediment to settle. Use only urine from the top of the container.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- Do not use after the expiration date printed on the foil pouch.
- Do not use if pouch is torn or damaged.
- Store in a dry place at 2-30°C or 36-86°F. Do not freeze.
- Keep out of the reach of children.
- Do not open the test foil pouch until you are ready to start the test.
- For in vitro diagnostic use. Not to be taken internally.
- The used test should be discarded according to local regulations.

【MATERIALS】

Materials provided: 1. Test Cassette; 2. Package Insert;

Materials required but not provided: 1. Specimen collection container; 2. Timer

【INSTRUCTIONS】

WHEN TO START TESTING

This kit contains 5 tests, allowing you to test over several days to find your most fertile time.

Calculate when to start testing using the chart below.

- First, determine your **Menstrual Cycle Length**. Your Menstrual Cycle Length is the number of days from the first day of your period (menstrual bleeding) to the last day before the next period starts.
- Next, determine the **Days to Count Ahead** after the period to start testing. Find the menstrual cycle length on the first row of the chart below, and read the corresponding number in the second row. This is the number of days after your period to begin testing.
- See the Example and Sample Calendar below to determine which day you should begin testing. First morning urine should **NOT** be used when testing for LH. For best results, you should test around the same time each day. You should reduce your liquid intake approximately 2 hours prior to testing.

When to Start Testing Chart

| Menstrual Cycle Length | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 |
|------------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Days to Count Ahead | 6 | 6 | 7 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |

Example: My usual cycle length is 28 days. My last period started on the 3rd. The "When to Start Testing Chart" shows that I will count ahead 11 days beginning with the 3rd. When I count 11 days ahead on the calendar, I find that I will collect and test my urine starting on the 13th.

○ First day of the last period

□ Begin testing with the LH Ovulation Test

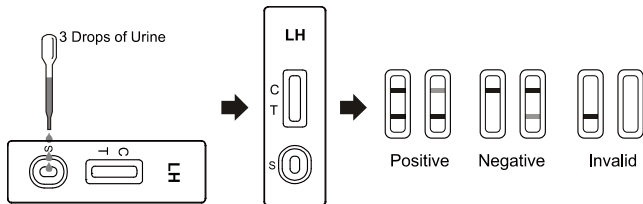
Sample Calendar

| S | M | T | W | T | F | S |
|----|----|----|----|----|----|----|
| | 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 | | | |

【DIRECTIONS FOR USE】

Determine the day you will begin testing using the "When to Start Testing Chart".

- Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.
- Bring the pouch to room temperature before opening it. Remove the Cassette test from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the sample dropper vertically and transfer 3 drops of urine (approx 120ul) to the specimen well of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
- Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not interpret the result after 10 minutes.



【READING THE RESULTS】

(Please refer to the illustration)

POSITIVE: Two lines are visible and the line in test line region (T) is the same as or darker than the line in the control line region (C). This indicates probable ovulation on in 24-36 hours.

NEGATIVE: Two lines are visible, but the line in the test line region (T) is lighter than the line in the control line region (C), or there is no line in the test line region (T). This indicates that no LH surge has been detected.

INVALID: Control line fails to appear. 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

- For self-testing in vitro diagnostic use
- This test may not be used as a form of birth control.
- The test results should not be affected by pain relievers, antibiotics and other common drugs. Medication containing hCG or LH may affect the test and should not be taken while using the LH Ovulation Rapid Test Cassette (Urine). In addition, the test will not work properly for subjects who are pregnant, in menopause, or taking birth control pills.
- Keep out of the reach of children.

【EXTRA INFORMATIONS】

1. Q: When can I do the test?

A: After you determine the best day to start testing based on your monthly cycle, you can do the test any time on that day. Testing with first morning urine is not recommended because it is concentrated and may give a false positive result. Testing between 10:00 AM and 8:00 PM is a good time frame, with many RES suggesting testing at 10:00 AM. Test at about the same time each day. Reduce your liquid intake for 2 hours before testing.

2. Q: Can I use the LH Ovulation Test to avoid pregnancy?

A: No, the test should not be used as a form of birth control.

3. Q: How accurate is the LH Ovulation Test?

A: A clinical evaluation was conducted comparing the results obtained using the LH Ovulation Test to another commercially available urine membrane LH test. The in-house clinical trial included 300 urine specimens. The results demonstrated >99.9% specificity and >99.9% sensitivity with an overall accuracy of >99.9%.

4. Q: What if no line appears in the Control region?

A: If no line appears in the Control region after 5 minutes, the result is invalid and you should repeat the test with a new Today Test. If the problem persists, please contact the manufacturer.

5. Q: I have tested for 7 days and I did not see a surge. What do I do?

A: Since every woman does not always ovulate at mid-cycle, you may not detect the LH surge in the first seven days of testing. This could mean you have not ovulated yet and you should continue testing with an additional Today LH Test.

6. Q: I have tested for 8 days or more and I still did not see my LH surge, what is wrong?

A: About 90% of ovulating women with regular cycles will see their surge during 8-10 days of testing. If you do not, it could mean that you have not ovulated this month. If you are having a short cycle this month, it is possible that you have ovulated before you started testing. If you are having a long cycle this month, you may not have ovulated yet. You may continue testing or test again next month. Don't worry, it is normal to have an occasional short or long cycle, or to have a cycle without ovulating.

7. Q: I have used the ovulation test for three months, and each month I have seen a surge and have had intercourse that day or night. I have not become pregnant yet. What is wrong?

A: First, it is important to remember that it can take normal, healthy couples many months to become pregnant. There are many factors that can affect your ability to become pregnant even if you have been able to have intercourse during your most fertile days. If after several months you have no success, consult with your physician or health care provider.

8. Q: What could interfere with my test result?

A: If you are already pregnant, have recently been pregnant, or have reached menopause you may get a misleading result. Some prescription drugs, such as menotropins for injection and Danazol may affect the results you see. Please consult your physician if you have any questions about prescription drug interactions.

9. Q: Will oral contraceptives affect the result?

A: After using the pill your cycle may be irregular and may take some time to stabilize again. You may wish to wait until you have had two normal periods before starting to use the Today Test.

10. Q: If the Today Test can determine my most fertile time, why can't I use it for contraception?

A: Sperm can survive up to 72 hours, and this test predicts your LH surge only up to 24 to 36 hours in advance. Therefore, if you have intercourse before you discover your surge, the egg can still be fertilized.

11. Q: How sensitive is the LH Ovulation Test?

A: The LH Ovulation Test detects luteinizing hormone (LH) in urine at concentrations of 40 mIU/mL or higher. Standard control calibrator use WHO NIBSC code: 80/552. The addition of FSH (1,000 mIU/mL), hCG (10,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL LH) and positive (40 mIU/mL LH) specimens showed no cross-reactivity.

12. 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, breastfeeding, or pregnancy could affect the test results.

13. Q: How long will the lines remain visible?

A: The test should be read at 3 minutes for best results. A positive (Surge) result will never disappear. The colored line(s) may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second color line because of evaporation from the test line. Therefore, you should not read the results after 10 minutes; discard the test once you have read the result.

14. Q: I am now using the basal body temperature method (BBT). Does this test replace BBT?

A: The LH Ovulation Test does not replace the BBT method. The shift in basal body temperature primarily indicates that ovulation has already occurred. The LH Ovulation Test indicates that ovulation is about to occur.

15. Q: I received a positive result and had intercourse during these fertile days but I have not become pregnant. What shall I do?

A: There are many factors that can affect your ability to become pregnant. It can take normal, healthy couples many months to achieve a pregnancy and often you may need to use the test kit for 3-4 months before achieving pregnancy. If pregnancy is not achieved after 3-4 months, you and your partner should consult your physician.

16. Q: I have had a positive result and had intercourse during these fertile days. I think I may be pregnant. How soon can I find out?

A: The HCG Pregnancy Test can provide you with results as early as the first day of your missed period.

【BIBLIOGRAPHY】

- Elkind-Hirsch, K; Golzdieher, JW; Gibbons, WE and Besch, PK. Obstetrics and Gynecology, 67(3): 450-453, 1986.

Index of Symbols

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|--|-------------------------------------|--|---------------|--|---------------------------|
| | Attention, see instructions for use | | Tests per kit | | Authorized Representative |
| | For in vitro diagnostic use only | | Use by | | Do not reuse |
| | Store between 2-30°C | | Lot Number | | Catalog # |
| | Do not use if package is damaged | | | | |

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