



LH OVULATION RAPID TEST DIPSTICK (URINE) FOR SELF-TESTING

INTENDED USE

The LH Ovulation Rapid Test Dipstick (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human luteinizing hormone (hLH) in urine to aid in the detection of ovulation. The result can be read visually in minutes to indicate a positive or negative result for 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 human luteinizing hormone (hLH) which triggers the release of a ripened egg from the ovary. This "hLH surge" usually takes place in the middle of the menstrual cycle.¹ The LH Ovulation Rapid Test Dipstick (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 Dipstick (Urine) detects the hLH surge in urine, signaling that ovulation is likely to occur in the next 24-36 hours. Important: The hLH surge and ovulation may not occur in all menstrual cycles.

PRINCIPLE

The LH Ovulation Test is a rapid lateral flow immunoassay for the qualitative detection of hLH 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 hLH antibody to selectively detect elevated levels of hLH.

The urine sample moves forward laterally on the test due to capillary forces. In the presence of hLH an immunological reaction between hLH and labeled anti-hLH antibodies takes place leading to a distinct red colored test line. Depending on the hLH concentration, the test line becomes lighter or darker. Other labeled antibodies from the control line. This reaction serves as a proof for the proper use and function of the test strip. This methodology is named immunochromatography.

REAGENT

The test contains anti-LH particles and anti-LH antibody coated on the membrane.

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.
- Use a new specimen collection container for every sample.
- 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 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 can be disposed off in normal household waste.
- For single use only.

STORAGE

The kit can be stored at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

MATERIALS

Materials provided: 1. Test Dipsticks; 2. Package Insert;
Materials required but not provided: 1. Specimen collection containers; 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.

- 1) 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.
- 2) 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.

- 3) 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.

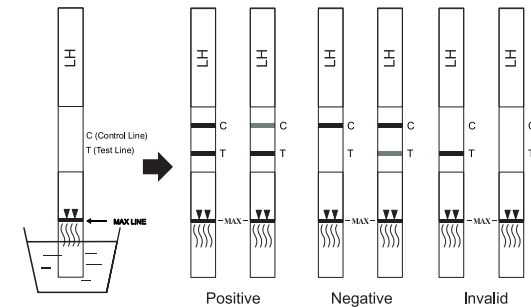
Sample Calendar						
S	M	T	W	T	F	S
	1	2	③	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

- First day of the last period
- Begin testing with the LH Ovulation Test

DIRECTIONS FOR USE

Determine the day you will begin testing using the "When to Start Testing Chart". A timer is needed to perform the test (not supplied).

1. Allow the test and urine specimen to reach room temperature (15-30°C) prior to testing.
2. Bring the pouch to room temperature before opening it. Remove the Dipstick test from the sealed pouch and use it within one hour.
3. With arrows pointing toward the urine specimen, immerse the test dipstick vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test dipstick when immersing the dipstick. See illustration below.
4. Place the test dipstick on a clean, dry, non-absorbent flat surface, start the timer and wait for the colored line(s) to appear.
5. Read results at 5 minutes. Do not interpret the result after 10 minutes. The used test can be disposed off in normal household waste.



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 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 hLH 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.
- Do not reuse the dipsticks
- The test results should not be affected by pain relievers, antibiotics and other common drugs.
Medication containing hCG or hLH may affect the test and should not be taken while using the LH Ovulation Rapid Test Dipstick (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 timeframe, 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 test. If the problem persists, please contact the manufacturer.

5. Q: I have tested for several 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 hLH surge in the first seven days of testing. This could mean you have not ovulated yet and you should continue testing with an additional LH Test.

6. Q: I have tested for 8 days or more and I still did not see my hLH 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 menopausal hormone therapy 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 Test.

10. Q: If the 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 hLH 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 human luteinizing hormone (hLH) in urine at concentrations of 30mIU/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 μ IU/mL) to negative (0 mIU/mL hLH) and positive (30mIU/mL hLH) 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

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

Index of Symbols

	Caution: read instructions (warnings) carefully		Manufacturer		Disposable device, do not re-use
	<i>In vitro</i> diagnostic medical device		Product code		Temperature limit
	Don't use if package is damaged		Lot number		Consult instructions for use
	<i>In vitro</i> diagnostic medical device compliant with Directive 98/79 / EC		Expiration date		Contains sufficient for "n" tests
	Authorized representative in the European community				

GIMA 29125



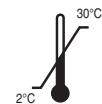
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