

OVULATION TEST - SELF TEST MIDSTREAM

Use and maintenance book

ATTENTION: Operators must read and understand this manual completely before using the product

GIMA 29124

Hangzhou AllTest Biotech Co., Ltd.
#550, Yin Hai Street
Hangzhou Economic & Technological
Development Area
Hangzhou - 310018, P.R. China
Made in China

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

REF FLH-M103H

EC REP MedNet GmbH
Borkstrasse 10 - 48163 Muenster
Germany



LH Ovulation Rapid Test Midstream (Urine) Package Insert

For Self-testing

A rapid test for the qualitative detection of luteinizing hormone (LH) in human urine.

INTENDED USE

The LH Ovulation Rapid Test Midstream (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.¹ The LH Ovulation Rapid Test Midstream (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 Midstream (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

The LH Ovulation Rapid 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 colored test line. Depending on the hLH concentration, the test line becomes lighter or darker. Other labeled antibodies are 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.
- 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 of in normal household waste.
- For single use only.

STORAGE AND STABILITY

Store as packaged 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. Avoid exposure to direct sunlight, humidity or heat.

MATERIALS

Materials provided

- Test Midstream
- Package Insert
- Specimen Collection Containers
- Timer

Materials required but not provided

INSTRUCTIONS

WHEN TO START TESTING

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.
- If your cycle is shorter than 21 days or longer than 38 days, consult your doctor. If you do not know your cycle length, you may begin the test 11 days after your first period since the average cycle length is 28 days.
- 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. Perform 1 test each day over a period, or until the hLH surge has been detected.

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 Rapid Test

Sample Calendar

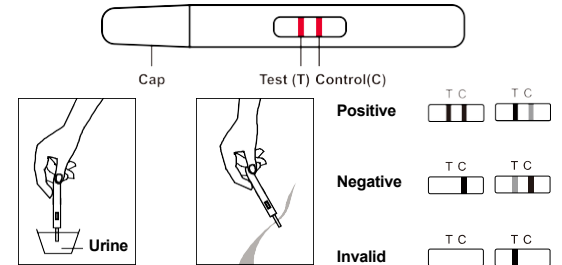
S	M	T	W	T	F	S
	1	2	③	4	5	6

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".

- Bring the pouch to room temperature (15-30 °C) before opening it. Remove the midstream from the sealed pouch and use it within one hour.
- Remove the Cap and hold the midstream by the Thumb Grip with the **exposed Absorbent Tip pointing downward directly into your urine stream for at least 15 seconds** until it is thoroughly wet. (See illustration below)
NOTE: Do not urinate on the Result Window. If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream test into the urine for at least 15 seconds.
- After removing the midstream test from urine, immediately replace the Cap over the Absorbent Tip, lay the midstream on a flat surface with the Result Window facing upwards, and then begin timing.
- As the test begins to work, you may notice a light colored flow moving across the Result Window. **Read the result at 3 minutes.** If no result appears, wait one minute longer. Do not read the result after 10 minutes.



READING THE RESULTS

POSITIVE: Two colored lines are visible, and the line in the Test Line Region (T) is the same as or darker than the line in the Control Line Region (C). This indicates that you will probably ovulate in 24-36 hours.

NEGATIVE: Two colored 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 and daily testing should be continued.

INVALID: The result is invalid if **no colored line appears** in the Control Line Region (C), even if a line appears in the Test Line Region (T). You should repeat the procedure with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

- For self-testing *in vitro* diagnostic use.
- This test may not be used as a form of birth control.
- Do not reuse the tests.
- 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. 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

- 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 researchers suggesting testing at 12:00 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 Rapid 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 Rapid Test?

A: A clinical evaluation was conducted comparing the results obtained using the LH Ovulation Rapid Test to another commercially available urine 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 3 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 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 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 Rapid Test?

A: The LH Ovulation Rapid Test detects human luteinizing hormone (hLH) in urine at concentrations of 35 mIU/mL or higher. The addition of FSH (1,000 mIU/mL), hCG (10,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hLH) and positive (35 mIU/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 colored 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 Rapid Test does not replace the BBT method. The shift in basal body temperature primarily indicates that ovulation has already occurred. The LH Ovulation Rapid 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 Rapid Test can provide you with results as early as the first day of your missed period.

	Contains sufficient for "n" tests
	Don't use if package is damaged
	Consult instructions for use

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies

Number: 145130604 Effective Date:2022-08-03











TEST RESULTS CHART

Test	Date	Collection Time	Result
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			

BIBLIOGRAPHY

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

Index of Symbols

	In vitro diagnostic medical device compliant with Directive 98/79 / EC
	Product code
	Manufacturer
	Lot number
	In vitro diagnostic medical device
	Expiration date
	Authorized representative in the European community
	Imported by
	Disposable device, do not re-use
	Temperature limit