

Luteinizing Hormone (LH) Ovulation Rapid Test Kit

For In Vitro Diagnostic Use

Ref: LHR01

Basic UDI-DI: 888130055201GA

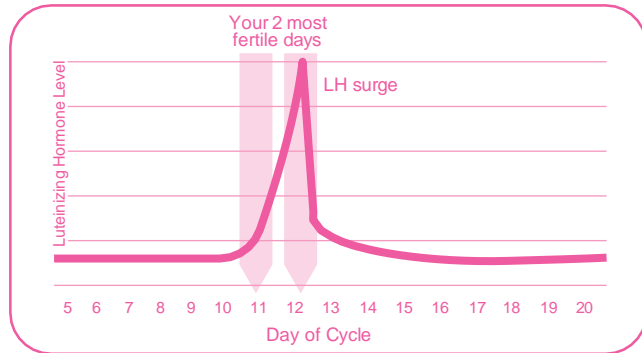
Intended use

Luteinizing Hormone (LH) Ovulation Rapid Test is a qualitative lateral flow immunoassay for the rapid detection of luteinizing hormone (LH) in urine for women of childbearing age, especially for those who want to conceive, to assist in diagnosing ovulation. It is intended for self-testing use.

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, and LH typically surges 24 to 48 hours prior to ovulation. LH is present in the serum and urine of healthy women according to the following chart:

Population		Range (mIU/ml)
Women after menopause		10-200
Women of childbearing age	Basel level	5-20
	Fastigium	40-200



Principle

The Luteinizing Hormone (LH) Ovulation Rapid Test is a chromatographic immunoassay for the rapid qualitative determination of LH in urine. The membrane is pre-coated with LH capture antibody on the test line (T line) and goat anti-mouse IgG polyclonal antibody on the control line (C line). During testing, the urine specimen is allowed to react with the coloured conjugate (mouse anti-LH monoclonal antibody-latex microsphere conjugate) which has been pre-dried on the membrane. The mixture then moves upward on the membrane chromatographically by capillary action.

For positive result, a red-coloured band with the specific antibody-LH-coloured conjugate complex will form in the T line of the membrane, and the colour intensity of the T line is as the same as, or stronger than that of the C line. This means that the concentration of LH in the urine sample is at a higher level.

For negative result, the colour intensity of the T line is weaker than that of the C line or there is no line in the T line. These test results mean that the concentration of LH in the urine sample is at a normal level. Regardless of the presence of LH, there should be a red line on the C line to prove that the product is working properly.

Reagents and materials supplied

- Test device (midstream)
- Instruction for use

Materials required but not supplied

- Timer
- (Optional) Specimen collection container

Storage and stability

Store the kit at 4-30°C away from direct sunlight. Kit components can be stored for 24 months when sealed in its original packaging. See the product label for lot number and expiration date.

Limitations

- If the menstrual cycle is irregular or unusual, consult a healthcare professional before using the device.
- Some prescription drugs, such as menotropins may affect the test result. Certain rare medical conditions or the onset of menopause can cause elevated levels of LH. Some women do not ovulate every cycle and they will not see any increase in the level of LH hormone during these non-ovulating cycles. Women with Polycystic Ovary Syndrome (PCOS) may not get reliable results from ovulation tests.
- Medication containing human chorionic gonadotropin (hCG) or LH may affect the test result, and the test may not work properly if the user is pregnant, menopausal, or taking birth control pills.
- Reduce liquid intake for 2 hours before testing, since drinking excessive amounts of liquids can dilute the LH in the urine, yielding a negative result when it should be positive.
- The Luteinizing Hormone (LH) Ovulation Rapid Test only detects the hormone surge that precedes ovulation; it can't tell if you will actually release an egg during your cycle.
- The Luteinizing Hormone (LH) Ovulation Rapid Test should not be used for contraception.

Specimen collection

- Determine the optimal time for urine collection. For best results, collect the urine at about the same time each day. It is recommended to collect urine between 10:00 AM to 8:00 PM. Some women have found that their best specimen is after 12:00 noon. Do not collect the first urine specimen after waking up.
- If urine needs to be collected in a collection container, use a new specimen container for every sample. 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.
- Record the date, cycle day, and time of urine collection in the Test Results Chart at the end of this package insert.

Test method

Please read the instructions for use carefully before testing.

When to start testing

- First, determine the Menstrual Cycle Length. Menstrual Cycle Length is the number of days from the first day of the period (menstrual bleeding) to the last day before the next period starts.
- Next, determine the number of Days to Count Ahead to know when to begin testing. Counting starts on day 2 of the menstrual cycle and testing begins on the day at the end of the count. Refer to the chart below to find the menstrual cycle length in the first/third row, and the corresponding number of Days to Count Ahead in the second/fourth row.
- If the cycle is shorter than 21 days or longer than 38 days, please consult a doctor. If the cycle length is not known, the test may be started 11 days after day 1 of the cycle since the average cycle length is 28 days.
- See the Example and Sample Calendar below to determine which day testing should begin. Perform 1 test each day over a period, or until the LH surge has been detected.

Start Testing Chart

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

Example: The usual cycle length is 28 days and the last period started on the 6th. The "Start Testing Chart" shows that the testing will begin on Day 11 after the 6th, which means urine will be collected and tested from the 17th according to the calendar.

Simulation Calendar

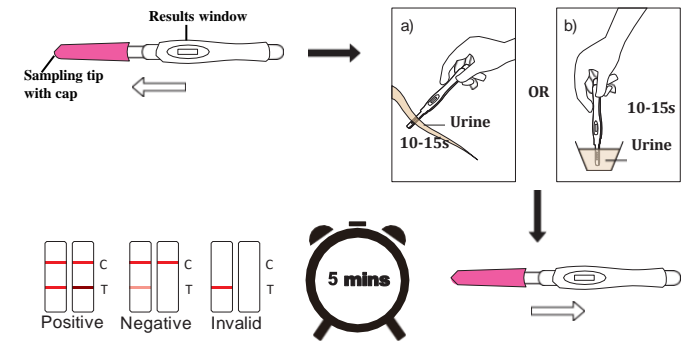
SUN	MON	TUES	WED	THU	FRI	SAT
29	30	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31	1	2

6 - First day of the last period;

17 - Begin testing with the Luteinizing Hormone (LH) Ovulation Rapid Test.

How to test

- Review "Specimen collection" instructions. The test device should be brought to room temperature prior to testing.
- Carefully wash your hands. Check the components of the kit and the expiry date at the back on the foil pouch. DO NOT use it after the expiration date.
- Remove the midstream test device from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed within one hour upon opening.
- Remove the cap of the test before use.
- Let the sampling tip touch the urine for 10-15 seconds (There are 2 methods, see the details below).
 - a) For direct test: Put the sampling tip of the test directly in midstream urine for 10-15 seconds. Note: Do not urinate on the result window.
 - b) For collected urine: Dip the sampling tip vertically into the specimen collection container containing urine (at least 2ml). During this period, the sampling tip might change colour as it sucks up the liquid. Note: Do not dip the sampling tip in the urine beyond the results window.
- Take out the test midstream from the urine and cap the test midstream. Place the test midstream horizontally with the test window facing upwards, and start the timer.
- Read the results 5 minutes later. Do not interpret results after 10 minutes. Please record the test result in the **Test Results Chart** at the end of this package insert.
- Dispose of used test kits in the same way as household waste, and wash hands thoroughly after test completion.



Interpretation of results



Positive

Two lines are visible and the T line is the same as or darker than the line in the C line region. This indicates probable ovulation in 24-36 hours.



Negative

Two lines are visible, but the line in the T line is paler than the line in the C line or there is no line in the T line but there is one line in the C line. This indicates that no LH surge has been detected.



Invalid

C 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 device. If the problem persists, discontinue using the test kit immediately and contact the local distributor.

Warning and Precautions

- The test works only if the instructions are followed precisely.
- For in-vitro diagnostic (IVD) use only. Not to be taken internally.
- Inadequate or inappropriate specimen collection, storage and transport may yield false results.
- The test device should remain in the sealed pouch until use. Please use this test as soon as possible after opening.
- Do not use the test if the inner packaging is found to be damaged or unsealed before use.
- Do not use the test kit if it was stored under unsuitable conditions.
- Do not use it after the expiration date.
- Do not reuse the test device.
- Do not read test results before 5 minutes or after 10 minutes. Results read before 5 minutes or after 10 minutes may lead to a false positive, false negative, or invalid result.
- Keep testing kit and kit components away from children and pets before and after use.
- Any serious incident that has occurred in relation to the device shall be reported to Camtech or a healthcare professional.

Performance characteristics

Analytical Sensitivity

The Luteinizing Hormone (LH) Ovulation Rapid Test detects urinary LH concentrations equal to or greater than 25mIU/ml (calibrated against WHO 2nd IS, 80/552).

Cross-Reactivity

The specificity of the Luteinizing Hormone (LH) Ovulation Rapid Test was determined from cross-reactivity studies with known amounts of Human chorionic gonadotropin (hCG), Follicle Stimulating Hormone (FSH), and Thyroid Stimulating Hormone (TSH). Negative results were obtained from all tests conducted with 200mIU/ml hCG, 200mIU/ml FSH and 250µIU/ml TSH.

Interference

There is no interference with the interfering substances listed below.

Substances	Concentration	Substances	Concentration
Carbamide	20 mg/dl	Acetone	2000 mg/dL
Uric acid	10 mg/dl	Hydroxybutyrate	2000 mg/dL
Creatinine	150 mg/dl	Acetoacetic Acid	2000 mg/dL
Glycine	2 mg/ml	Acetaminophen	20 mg/dl
β-aminoisobutyric acid	2 mg/ml	Acetylsalicylic Acid	20 mg/dl
Taurine	2 mg/ml	Gentisic Acid	20 mg/dl
Hemoglobin	200 g/L	Ascorbic Acid	20 mg/dl
Albumin	20 mg/dL	Tetracycline	20 mg/dl
Bilirubin	400 µmol/mL	Ampicillin	20 mg/dl
Estradiol	1400 µg/dL	Alcohol	20mg/dl
Pregnanediol	1500 µg/dL	Caffeine	20mg/dl
Glucose	2 g/dl		

Hook Effect

No hook effect when the concentration is at 500 mIU/mL and below.

Clinical Performance

		LH commercial equivalents		Total
		Positive	Negative	
Camtech test	Positive	71	1	72
	Negative	1	102	103
Total		72	103	175

Questions and answers

1. Q: Will alcohol, aspirin, paracetamol, or any other common drug affect the test?

A: No, but some hormonal medications can interfere with test results. If such medications are being taken or are suspected, seek professional advice from a physician to confirm the test results. Drugs containing hCG or LH can affect the test results, and clomid can cause false positives if you begin testing too early in your cycles.

2. 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.

3. Q: Can I use the Luteinizing Hormone (LH) Ovulation Rapid Test to avoid pregnancy?

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

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

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

5. 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 recent evidence suggesting testing at 12:00 noon. Test at about the same time each day. Reduce your liquid intake for 2 hours before testing.

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

A: The test should be read at 5 minutes for best results. A positive result (surge in LH) will never disappear. The coloured line(s) may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second colour line because of evaporation from the test line. Therefore, it is noteworthy that the results should not be read after 10 minutes.

7. Q: What if the Control line does not appear?

A: If the Control line does not appear after 5 minutes, the result is invalid and you should repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact the local distributor.

8. Q: Today's control line is a different shade of red than yesterday's control line. Is this a concern?

A: No. Variations in the colour of the control line will not affect the test result. Always compare the colour of the test line to that of the control line of the same device on the day the test is performed. Do not compare bands from different devices.

9. Q: If I am still uncertain when the test result is positive, what shall I do?

A: If you are still uncertain when the test result is positive, try the following. During one cycle, when your kit shows you are ovulating, continue to test your urine even after ovulation has passed. This will help you see the maximum darkness of your T line. Knowing that the ovulation signal (LH surge) only lasts 48-60 hours, your T line will eventually start to fade away if you continue testing after ovulation. Seeing this line fade will help you know the peak darkness of your T line and give you more confidence in pinpointing your most fertile time.

10. Q: How long should I continue to perform the test?

A: Unless a doctor or a healthcare professional suggests differently, stop testing once the LH surge is detected. Five to ten days of testing may be

needed to detect the LH surge, though additional testing may be required.

11. Q: Once I detect my LH Surge, when is the best time to have intercourse?

A: Your most fertile days begin with the LH Surge. You are most likely to get pregnant if you have intercourse within 24-48 hours after you detect your LH Surge.

12. Q: I have been testing for 7 days or longer and I did not see a surge, what is wrong?

A: About 90% of ovulating women with regular cycles will see their surge during 5-10 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.

Test Results Chart

Test	Date	Collection time	Result
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			
Day 8			
Day 9			
Day 10			

Product Owner

Camtech Diagnostics Pte. Ltd.

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Index of symbols

	Consult instructions for use		Use-by date
	In vitro diagnostic medical device		Lot number
	Catalogue number		Keep away from sunlight
	Store at 4-30°C		Do not re-use
	Do not use if package is damaged		Contains sufficient for $n-1$ tests
	Keep dry		

Instructions Manual Version and Date

Version No.: LHR01 IFU 2401

Effective Date: 25.01.2024