



Ovulation Test

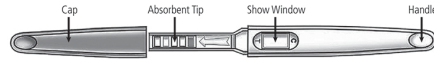
PRINCIPLE

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 Ovulation Test is a rapid, one-step lateral flow chromatographic immunoassay for the qualitative detection of LH surges in urine, signalling that ovulation is likely to occur in the next 24-36 hours. The test utilises a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH. The test is conducted by urinating on the absorbent tip and obtaining the results from the coloured lines.

PRECAUTIONS

Please read all the information in this package insert before performing the test. Pay particular attention to the position of the C and T lines.

- Do not use after the expiration date printed on the foil pouch.
- Store in the sealed pouch in a dry place at 4-30°C. Do not freeze.
- Do not use if pouch is torn or damaged.
- Do not open the foil pouch until you are ready to start the test.
- Do not reuse the test device. Dispose of hygienically in domestic waste.
- Do not touch the membrane located in the windows.
- Treat urine samples and used devices as potentially infectious. Avoid contact with skin.
- Keep out of the reach of children.
- For *in vitro* diagnostic use. Not to be taken internally. Do not eat the desiccant in the package.



KIT CONTENTS

- 5 Midstream tests (each in foil pouch)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Specimen Collection Container
- Disposable gloves

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. Determine the length of your menstrual cycle by counting the number of days from the first day of your period (menstrual bleeding) to the last day before your next period starts. Think back over the last few months to decide what your usual cycle length has been. On the chart below, read the day to start testing corresponding to your cycle length.

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
Start test on day	6	6	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

Note: If you are unsure about your cycle length, you may want to use your shortest cycle length when reading the chart. However, if you do this, you may need to test for more than 5 days.

Example: If your usual cycle length is 28 days according to the "When to Start Testing Chart" begin testing on day 11 of your cycle. If your last period started on the 3rd day of the month, count ahead 11 days and you should begin testing on the 13th day of the month.

Key:

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

Sample Calendar

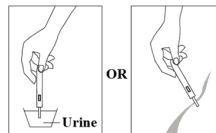
S	M	T	W	T	F	S
	1	2	③	4	5	6
7	8	9	10	11	12	⑬
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

SPECIMEN COLLECTION AND PREPARATION

Determine the optimal time for urine collection. For best results, collect urine at about the same time each day, reduce liquid intake approximately 2 hours prior to urine collection. Do not use first morning urine.

INSTRUCTIONS

- Allow the Ovulation test to reach room temperature (15-30°C) before opening the foil pouch.
- Remove the Ovulation test from the pouch and use it as soon as possible (use within one hour).
- Remove the cap to expose the absorbent tip.
- Hold the test by the thumb grip with the exposed absorbent tip pointing downwards. Urinate on the absorbent tip until it is thoroughly wet (15 seconds). See illustration at right. **NOTE: Do not allow urine to come into contact with the Result window.**
- Lay the test on a flat surface with the window on top and wait for the red line(s) to appear.
- Read the result at 3 minutes. Do **not** read the result after 10 minutes.



READING THE RESULTS

- POSITIVE**
Two lines are visible and the Test Line (T) is the same as or darker than the Control Line (C). This indicates that the urine sample has been taken within 24-36 hours of the LH surge.
- NEGATIVE**
Two lines may be visible but the Test Line (T) is lighter than the Control Line (C). Alternatively, the Test Line is not visible. This indicates that the LH surge has not been detected. You should continue daily testing.
- INVALID**
The result is invalid if the Control Line (C) fails to appear. Insufficient volume of urine or incorrect procedure is the most likely reason for an invalid result. Review the procedure and repeat the test with a new test kit. If the problem persists, discontinue using the test kit and contact the Customer Care Line below.

QUALITY CONTROL

A red-purple line appearing in the control region (C) confirms that the test is performing properly. It indicates that sufficient urine has been applied to the absorbent tip and that the correct procedure has been carried out.

LIMITATIONS

- The reagents used in the test cross-react with human chorionic gonadotropin (hCG). The test is only intended for the detection of LH in hCG-free samples.
- The test will not work properly if you are pregnant, menopausal, or taking birth control pills.
- Women suffering from polycystic ovary syndrome may have elevated LH concentrations.
- Test results should not be affected by common pain relief medication.
- Antibodies containing hCG or LH may affect the test results.
- Do **NOT** take any medical decision based on the results of this test without consulting your doctor.
- This test should not be used as a form of birth control.
- The Ovulation Test is not reusable.

QUESTION & ANSWERS (Call our Customer Care Line 0800 0430318)

- Q: Can I use the Ovulation Test to avoid pregnancy?**
A: No, the test should not be used as a form of birth control.
- Q: How accurate is the Ovulation Test?**
A: The accuracy of the test is 99%.
- Q: How sensitive is the Ovulation Test?**
A: The test detects LH in urine at concentrations of 35mIU/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 LH) and positive (35 mIU/mL LH) specimen showed no cross-reactivity.
- Q: Does alcohol or common medications affect the test?**
A: No, but you should consult your doctor if you are taking any hormonal medication. Also, recent oral contraceptive use or pregnancy can affect the test results. At the concentrations shown, none of the following substances affected the test results: Acetaminophen (Paracetamol 20mg/dL), Acetylsalicylic acid (Aspirin 20mg/dL), Ascorbic acid (Vitamin C 20mg/dL), Atropine (20mg/dL), Caffeine (20mg/dL), Gentamicin (20mg/dL), Glucose (2g/dL) and Haemoglobin (1mg/dL).
- Q: What time of day should I perform the test?**
A: Test about the same time each day for the entire cycle. Testing with first morning urine is not recommended because it is concentrated and may give a false positive result. Reduce your liquid intake for 2 hours before testing.
- 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 ovulation test. If the problem persists, please contact our customer care line.
- 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 coloured line(s) may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second 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.
- Q: Once I see a positive result, when is the best time to have intercourse?**
A: Ovulation is likely to occur within approximately 24-36 hours. This is your most fertile time and intercourse is advised within this time frame.
- 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. It can be normal to have an occasional short or long cycle, or to have a cycle without ovulating.
- Q: I received a positive result and had intercourse during these fertile days but I have not become pregnant?**
A: It can take normal, healthy couples many months to achieve a pregnancy. If you are concerned about you or your partners fertility you should consult your doctor.

[BIBLIOGRAPHY]

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

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 4-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use



FLH-M103H
146046400
Rev. 04/19



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