

Ovulation Rapid Test Strip

INSTRUCTIONS FOR USE

PLEASE READ ALL INFORMATION IN THE INSTRUCTIONS FOR USE BEFORE USING THE TEST!

REF See Box label

INTENDED USE

Amazewell™ Ovulation Rapid Test Strip is used for qualitative detection of Luteinizing Hormone (LH) in human urine as an aid in the prediction of ovulation. It is an IVD medical device intended for home use by lay person.

Only for use outside the body. For over-the-counter (OTC) use.

HOW DOES IT WORK?

When urine specimen is added into the sample pad of strip, capillary action carries the specimen to migrate along the membrane. When LH in the specimen reaches the Test area (T) of the membrane, it will form a colored line. The color depth of the Test line is positively correlated with the LH level in the specimen. To serve as a procedure control, a colored line will always appear at the Control area (C) if the test has been performed properly.

KIT CONTENT

Material provided

1. One pouch containing a test and a bag of desiccant.
2. Leaflet with instructions for use.

Materials needed but not provided

1. A urine collection cup to collect the urine.
2. Timer or clock.

WARNING AND PRECAUTIONS

1. This product is only for in vitro testing of human urine. **Not** for internal use.
2. This product is for single-use. Please use within the validity period. **Do not re-use.**
3. It's recommended to test at the same time every day for best results.
4. It's recommended to use the same batch of test strips in the same testing cycle.
5. **DO NOT** drink too much water or other beverages prior to testing.
6. Ovulation is a complex physiological process. Sometimes the appearance of LH peak does not necessarily lead to the normal production of corpus luteum after ovulation. If the LH peak is measured and the sexual intercourse is normal, and there is still no pregnancy after 3 months, you should consult your doctor.
7. Taking contraceptive pills will affect the test results, so this product can only be used after stopping the pills for three months.
8. The desiccant in the packaging pouch is for storage purposes only. **DO NOT** swallow.
9. Please follow local regulations to discard used product.
10. **DO NOT** use the product if damaged or its pouch is punctured or not well sealed.
11. **DO NOT** use the product after the expiration date.

12. **DO NOT** use the product in outdoor environment.

13. If the product is taken out of the refrigerator, it should be returned to room temperature before opening the package for use.

STORAGE CONDITIONS AND SHELF LIFE

1. Store the test kit at 35°F - 86°F (2 - 30°C) up to the expiration date printed on package. Do not freeze.
2. Please use the test strip within one hour once opened.

SAMPLE REQUIREMENTS

1. The urine shall be collected with a urine collection cup or a clean container. Please perform the test immediately after urine collection. If immediate testing is not available, the urine should be stored at 35°F - 46°F (2 - 8°C) for not more than two days. Restore the urine to room temperature before the test.
2. Avoid drinking plenty of water or other liquid 2 hours before urine collection in order not to affect the detection of LH Peak.
3. Urine samples can be collected anytime between 10:00 am and 8:00 pm. We recommend collecting the urine sample at about the same time each day. Do not collect the first morning urine.

WHEN TO START TEST

1. Determine the length of your menstrual cycle before testing. A menstrual cycle refers to the duration calculated from your first menstrual bleeding day to the day before the next bleeding begins. Women with menstrual cycles of varying lengths may determine their cycle days based on the shortest period of their last 3 menstrual cycles.
2. Determine the test start date. Refer to the table below to determine when you should start testing. Perform the test once a day for 5 - 10 consecutive days until the LH surge is detected. For example, if your last menstrual cycle is 25 days, your first menstrual bleeding day of this cycle is taken as day 1 and you may start testing on day 8 of this cycle. If your cycle is shorter than 21 days or longer than 40 days, consult a physician. If you do not know your cycle length, you may start testing on day 11 after your first period since the average cycle length is 28 days.
3. It is recommended to test twice a day, once around noon and again in the early evening.

Table 1 Menstrual Cycle Chart

Menstrual cycle (days)	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
Date to start test (date)	6	6	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23

HOW TO PERFORM THE TEST

The test should be performed at room temperature (59°F - 86°F / 15°C - 30°C).

1. Remove the test strip from the sealed pouch. **Caution: DO NOT touch the sample pad and result window.**
2. Hold the test strip vertically, dip the sample pad of the test strip into the urine with the arrow pointing towards the urine (Fig.2). Keep the sample pad in the urine at least 5 seconds until the dye rises into the result window. **Caution: DO NOT dip past the MAX line. Make sure that the rest of the test strip does not get wet.**
3. Take the test strip out and lay it flat on a clean, dry, and non-absorbent surface with the MAX line side facing upwards, and then begin timing. **Caution: Never hold the test strip with the sample pad pointing upwards (Fig.3).**
4. Read the results at 5 minutes (Fig.4). **DO NOT** read results after 10 minutes.

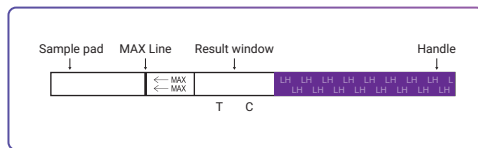


Fig.1 Construction of the test strip

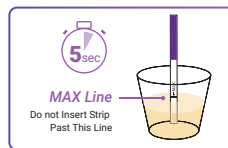


Fig.2 Test in a urine container

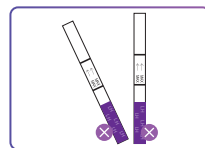


Fig.3 Never hold the test strip with the sample pad pointing upwards



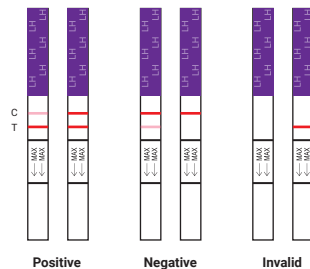
Fig.4 Wait 5 minutes to read results

READ YOUR RESULT

Negative (No LH Surge): Only ONE colored line appears in the Control Zone (C), or the Test line appears but is lighter than the Control line. This means there is no LH surge, and continuous monitoring is required.

Positive (LH Surge): TWO distinct colored lines appear, and the Test line is equal to or darker than the Control line, you have detected your LH surge and have reached your most fertile time. Having intercourse at any time during the next 24 - 48 hours to maximize your chance of becoming pregnant.

Invalid: No colored line appears in the Control Zone (C), or there is a colored line only appears in the Test Zone (T) but not in the Control Zone (C). Repeat with a new test strip. If test still fails, please contact the local distributor or the manufacturer with the lot number.



Positive

Negative

Invalid

QUESTIONS & ANSWERS

1. Who is suitable for this product?

This product is suitable for those who have normal menstrual periods and want to predict ovulation. Menopausal women and pregnant women are not suitable for use. If the LH peak lasts for several days, you should first test for pregnancy.

2. There is much difference between the Control lines of two different ovulation tests. Is this a concern?

No. Variations in the color of the Control line will not affect the test result. It is only effective to compare the color of the Test line to that of the Control line of the same test.

3. How long should I continue to perform the test?

At least 5 days or until the LH surge has been detected.

4. Can any medication or medical conditions affect the test result?

Drugs for infertility treatment and contraceptive pills may affect the accuracy of test results. Particularly, taking contraceptive pills should be stopped for three months before LH testing. You should consult your physician if you are taking any medication. Also, some means of contraception where hormones are used, such as subcutaneous implants, contraceptive patches, hormonal IUDs, or vaginal rings, can affect your test results.

Test results of this product are not affected by chyluria, haematuria, bilirubinuria, and proteinuria. High levels of chyle may affect test results.

5. Once I see a positive result, when is the best time to have intercourse?

Ovulation is likely to occur within 24 - 48 hours. This is your most fertile time. Sexual intercourse within this time frame is recommended.

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

The rising in basal body temperature primarily indicates that ovulation has already occurred. This test indicates that ovulation is about to occur.

7. I have received a positive result and had intercourse during these fertile days. But I have not become pregnant. What shall I do?

Many factors can affect your ability to become pregnant. Often you may need to use the test kit for 3 months. You and your partner should consult your physician if pregnancy is not achieved after 3 months.

8. Can test results be interpreted after more than 10 minutes?

No. Test results must be read within 10 minutes. A negative result may change to a false positive within minutes after the end of the 10-minute testing period, which would not be an accurate reading. It is always best to read the result between 5 and 10 minutes and then discard the test to avoid confusion.

9. Since it tells me when I am fertile, can I use Amazewell™ Ovulation Rapid Test Strip as a contraceptive?

No. Amazewell™ Ovulation Rapid Test Strip is not for contraceptive use.

10. How accurate is this product?

Amazewell™ Ovulation Rapid Test Strip is over 99% accurate at detecting the LH surge.

LIMITATION

- This product is only suitable for the monitoring of luteinizing hormone levels in urine as an aid in the prediction of ovulation. It is not intended for the confirmed diagnosis of ovulation, nor for the detection of luteinizing hormone associated with hormone secretion disorders.
- The test provides only qualitative preliminary results and is not designed to determine the exact concentration of luteinizing hormone in the urine. Secondary analytical methods must be used to obtain accurate quantitative results.

PERFORMANCE CHARACTERISTICS

Sensitivity: 25 mIU/mL

Specificity: Test results for the specimens containing 200 mIU/mL FSH or 250 μ IU/mL TSH should both be negative.

ASSISTANCE

Call toll-free (888) 695-5248 (Monday - Friday 9:00 am - 5:00 pm, EST) or email to support@dochekusa.com.

Any serious incident related to the device shall be reported to the manufacturer and the competent authority in your country.

REFERENCES

- [1] Chen Yanru, Lin Junmin, Hou Quanling, Chen Siyao, Liu Lianlian, Lu Yingli. Application of luteinizing hormone in ovulation[J]. China Maternal and Child Health Care, 2018,33(04):951-954.
- [2] GB/T 18990-2008 Luteinizing hormone(LH) test strip (Colloidal gold immunochromatographic assay)[S]. CFDA, 2009.
- [3] Lounage E, Engrang P, Howles CM, et al. Assessment of the role of serum luteinizing hormone and estradiol response to follicle-stimulating hormone on in vitro fertilization treatment outcome[J]. Fertil Steril, 1997,67:889.
- [4] Esposito MA, et al. Role of periovulatory luteinizing hormone concentrations during assisted reproductive technology cycles stimulated exclusively with recombinant follicle-stimulating hormone. Fertil Steril. 2001 Mar;75(3):519-24.

MEANING OF SYMBOLS ON PACKAGE

	Consult instructions for use		Keep dry
	Store at 35°F - 86°F (2°C - 30°C)		Keep away from sunlight
	Use-by date		Catalogue number
	Batch code		Do not reuse
	In vitro diagnostic medical device		Do not use if package is damaged

Distributed By:

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