Amazewell™

Semi-Quantitative 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™ Semi-quantitative Ovulation Rapid Test Strip is used for semi-quantitative 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. By comparing with the color chart provided, semi-quantitatively determine the LH level. 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. Pouch containing a test strip and a bag of desiccant
2. Color chart
3. 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. Reuse is **NOT** allowed.
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 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 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 an LH peak 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 continuously at intervals of every 4 hours or at least twice a day when an LH peak is detected so as not to miss your most fertile days.

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 for 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 result at 5 minutes (Fig.4). ***DO NOT*** read results after 10 minutes.

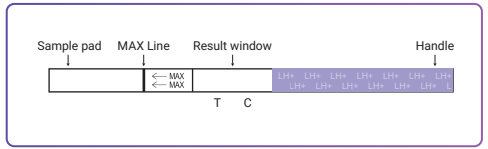


Fig.1 Construction of the test strip

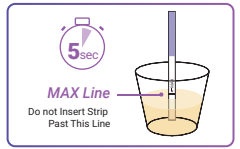


Fig.2 Test in a urine container

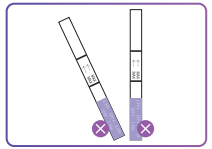


Fig.3 Never hold the test strip with the sample pad pointing upwards

Fig.4 Wait 5 minutes to read results

HOW TO READ AND RECORD YOUR RESULT

No Control line appears: It indicates an invalid result. Repeat with a new test strip.

Only Control line appears, but no Test line: Record the LH level as 0 on the timetable and record the test date.

Both Control line and Test line appear: Lay the test strip under the window slot of the color chart. Compare Test line to reference line and record the LH level corresponding to the closest color depth (Fig.5). *Caution: If the color depth of the Test line is between two color scales, take the middle value or take an estimated value.*

Note: Write down the LH value measured every day on the table of the color chart and draw a point on the corresponding position. Connect the points in order to get a curve of LH level changes to find the LH peak.

***Results interpreted by the color chart provided in the test kit is prevailed.**

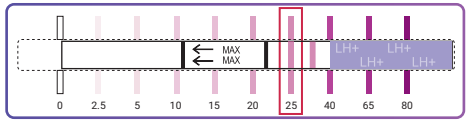


Fig.5 Compare the test line with the reference line to read your LH value

INTERPERTATION OF YOUR RESULT

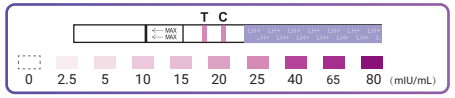
• If only Control line (C) appears or the color depth of Test line (T) is lighter than that of 2.5 mIU/mL, it means that the LH level in the specimen is lower than 2.5 mIU/mL.

• If the color depth of T line is between 2.5 mIU/mL and 80 mIU/mL, compare with the color chart to obtain a value.

• If the color depth of the T line is darker than the 80 mIU/mL, it's indicating the LH level in the specimen is higher than 80 mIU/mL.

① **Reference curve of LH changes in normal ovulation**

Luteinizing hormone (LH) is a hormone whose concentration varies periodically with a woman's menstrual cycle. Taking the day of ovulation as Day 0, the LH level fluctuated between 5 mIU/mL and 10 mIU/mL at the initial stage of follicle development. The LH value will rise to 20 mIU/mL to 25 mIU/mL at Day -2. When at Day -1, LH increases suddenly and sharply, forming the LH peak, the peak value is between 40 mIU/mL and 100 mIU/mL, and its level varies with each individual's physical difference. Ovulation will occur within 24 to 48 hours of reaching the LH peak. On the day of ovulation (Day 0), most people's LH level drops to a basal concentration of 10 mIU/mL and 25 mIU/mL, and drops to less than 10 mIU/mL on Day +1. Women of childbearing age can refer to Fig.6 to choose the best time to conceive. Ovulation is approaching when the LH peak is present evidently.



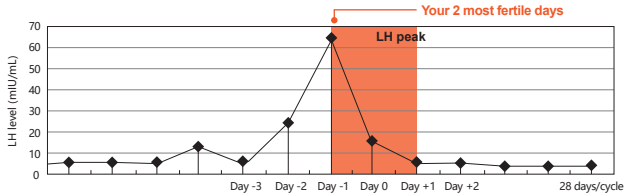


Fig.6 Reference curve of LH changes in normal ovulation

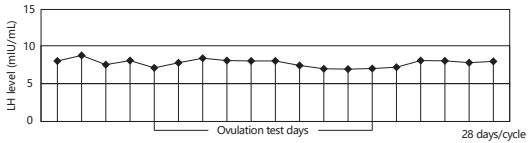


Fig.7 Reference curve of LH changes in abnormal ovulation

② **Reference curve of LH changes in abnormal ovulation**

Anovulation occurs when the ovaries stop ovulating due to a hormonal imbalance. The LH level of those with abnormal ovulation is low, which hovering between 5 mIU/mL and 10 mIU/mL, and there is no LH peak. The test result curve is similar to Fig.7, suggesting the possibility of anovulation. It is recommended to consult a specialist after testing again in the next cycle.

METROLOGICAL TRACEABILITY

The units measured are traceable to the units of the NIBSC 3rd International Standard for LH NIBSC coded 81/535.

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. How long should I continue to perform the test?
   At least 5 days or until the LH peak has been detected.
3. 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, haematuresis, bilirubinuria, and proteinuria. High levels of chyle may affect test results.
4. Once I find the peak, 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.
5. If I find I have more than one peak, after which peak did I ovulate?
   Ovulation occurs after the last peak, whether you have two or more peaks. In fact, many women have two peaks. It is quite common.
6. I have found the LH peak 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.
7. Can test results be interpreted after more than 10 minutes?
   No. The actual test result will be invalid after 10 minutes. It is always best to read the result between 5 and 10 minutes and then discard the test to avoid confusion.
8. Since it tells me when I am fertile, can I use Amazewell™ Semi-quantitative Ovulation Rapid Test Strip as a contraceptive?
   No. Amazewell™ Semi-quantitative Ovulation Rapid Test Strip is not for contraceptive use.
9. How accurate is this product?
   Amazewell™ Semi-quantitative Ovulation Rapid Test Strip is over 99% accurate at detecting the LH peak.

LIMITATION

1. 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.
2. The test provides only semi-quantitative 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: 2.5 mIU/mL
Specificity: No colored line appears in the Test area (T) when testing specimens containing 200 mIU/mL FSH or 250 μIU/mL TSH.

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] Zheng Qiuheng, Hu Lizhen. Clinical application of LH peak measurement to predict ovulation. Fujian Medical Journal, 1991,13(5):9-10.
[3] Sui Xiaolin, Song Xueru, Zhaoxiaohui, et al. Application of semi-quantitative determination of urinary luteinizing hormone in artificial insemination and assisted pregnancy technology to accurately predict ovulation. Journal of Tianjin Medical University, 2004,10(2):212
[4] Lournage 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 Setril, 1997,67:889.
[5] 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	35°F - 86°F	Store at 35°F - 86°F (2°C - 30°C)		Keep away from sunlight
Use-by date	REF Catalogue number	LOT	Batch code		Do not reuse
IVD *In vitro* diagnostic medical device	Do not use if package is damaged				

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2097 London Road Suite D, Delaware, OH, 43015
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