

Pregmate Ovulation Test is an in vitro diagnostic home use test device used to predict when there is a Luteinizing Hormone (LH) surge, and in turn, when you are likely to ovulate. For in vitro diagnostic home use only. For external use only.

HOW DOES IT WORK?

Luteinizing Hormone (LH) is one of the hormones produced by the pituitary gland. It is secreted at very low levels throughout your menstrual cycle. Once a developing egg follicle reaches a certain size, LH secretion surges to high levels. This hormone surge is what triggers ovulation 24-48 hours later.

When the sample end of the test is dipped into the urine specimen, the urine specimen is applied to the strip and migrates along the strip. When LH in the sample reaches the Test Zone region of the membrane, it will form a colored line. Absence of this colored line suggests a negative result. A colored line will appear at the Control Zone region if the test has been performed properly.

LH surge initiates the beginning of ovulation. Ovulation is the release of a mature egg from the ovary. It signals the beginning of your fertile period. A positive result indicates the presence of a high amount of LH or LH surge. The amount of LH in your body will begin to decrease after ovulation so you'll only get a positive result during that crucial fertile period. Once the egg is released it is only viable for about 24 hours. After that your fertile window is over. This makes it very important to be able to identify this best time to conceive.

Ovulation may be irregular because of conditions, emotions and other factors in your life. You can't presume that ovulation always occurs at the same time after menstruation. Therefore, you should test again in each menstrual cycle.



CONTENT OF THE TEST KIT

One pouch containing a reagent strip and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures. Leaflet with instructions for use.

WHAT ELSE DO YOU NEED?

A clean, dry, plastic or glass container to collect the urine. Timer (watch, clock or smartphone).

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test strip cannot be used more than once.
3. Do not use the test past the expiration date printed on the foil pouch.
4. Do not use the kit if the pouch is punctured or not sealed.
5. Keep out of the reach of children.

STORAGE AND STABILITY

1. Store at 39°F to 86°F (4°C to 30°C) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture, heat.
3. DO NOT FREEZE.
4. You should perform the test soon after opening the pouch. You should keep the test in a dry place before use.

WHEN TO COLLECT URINE FOR THE TEST?

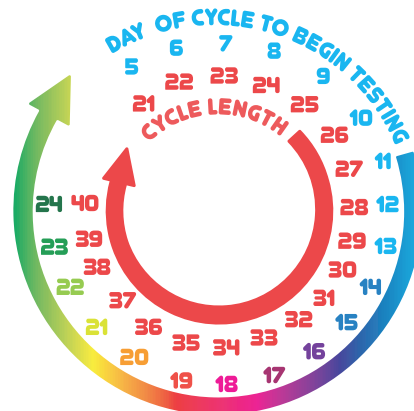
Any urine specimen is appropriate for ovulation testing. You should reduce your liquid intake approximately 2 hours prior to testing.

HOW TO COLLECT THE URINE SAMPLE?

Urine may be collected in any clean, dry plastic or glass container.

WHEN TO BEGIN TESTING?

The length of the menstrual cycle is the duration from your first menstrual bleeding day to the day before the next bleeding begins. Determine the length of menstrual cycle before test. Please refer to the chart below to determine when you should start testing. 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.



Example: If your cycle length is normally 26 days, the chart indicates testing should begin on day 10.

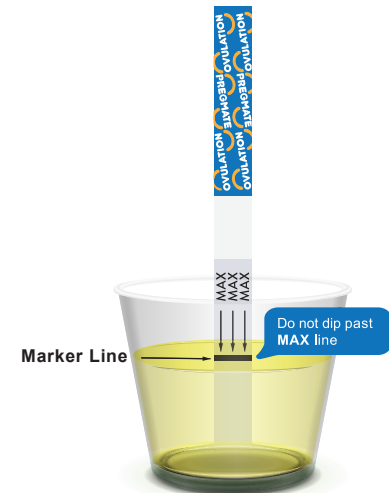
Note: This test is designed to work for cycles of different lengths. Remember you may not ovulate at the same time every cycle and that the cycle may vary from month to month. You may need to test over the next few months to find out your personal cycle length average.

HOW TO DO THE TEST?

1. The test strip and urine have to be at room temperature 59-86°F (15-30°C) for testing.
2. Remove the test strip from the sealed pouch.
3. Immerse the strip into the urine with the arrows pointing towards the urine. Take the strip out after 3-5 seconds and lay the strip flat on a clean, dry, non-absorbent surface.

IMPORTANT: Do not allow the urine level to exceed the MAX (marker line), otherwise the test will not perform correctly.

4. Read results in 5 minutes.

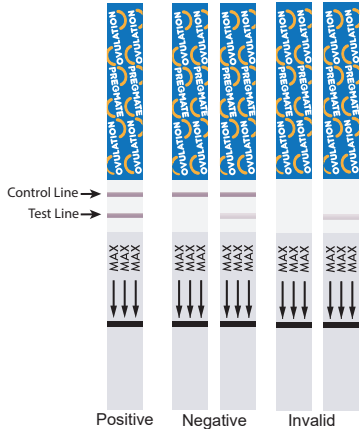


HOW TO READ THE RESULTS?

Positive (LH Surge): If two lines are visible, and the test line is equal to or darker than the control line, one will probably ovulate in the next 24-48 hours. If trying to get pregnant, the best time to have intercourse is after 24 but before 48 hours.

Negative (No LH Surge): No test line or test line is lighter than the control line.

Invalid: No visible line or there is a visible line only in the test zone and not in the control zone.



LIMITATIONS

- 1. The test works only when the test procedures are precisely followed.
- 2. This test may not be used as a form of birth control.
- 3. Consult a doctor if irregular or unusually long cycles are experienced.

QUESTIONS AND ANSWERS

Can test results be interpreted after more than 5 minutes?
No. Test results must be read at 5 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading. It is always best to read the results at the 5-minute testing period and then discard the test to avoid confusion.

There is much difference between the control lines of two tests. Is this a concern? No. Variations in the color of the control line will not affect the test result. You should always compare the color of the test line to the color of the control line of the same device on the day the test is performed.

A pink background color and vertical streaking appeared in the result area during the testing period. Is this a concern? No. Each urine sample will vary in its chemical makeup, as will the humidity of the air in testing room. Such variations in physical conditions can cause vertical streaking and pink-rose background color but will not affect the test results. If the control band appears within 5 minutes, the test is working properly.

How long should I continue to perform the test?
At least 5 days or until the LH surge has been detected.

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 the most fertile time. Sexual intercourse is advised within this time frame.

Can any medication or medical condition affect the result?
Certain medical conditions and medications can adversely affect the performance of the test: for example, if you are actually pregnant, have recently been pregnant, have reached menopause or have polycystic ovarian syndrome you may get a misleading result. This may also be true if you are taking fertility drugs containing Luteinizing Hormone or Human Chorionic Gonadotrophin (such as Pregnyl® and Profasi®). Clomiphene citrate (Clomid®) does not affect the tests, but may affect the length of your cycle and, therefore, when you should be testing.

Will oral contraceptives affect the result? After using oral contraceptives, your cycle may be irregular and take some time to stabilize again. You may wish to wait until you have had two or more normal menstrual cycles before starting to use this test.

If the ovulation test can determine when I am fertile, can I use it for contraception and birth control? We do not recommend using ovulation tests for birth control or as means of contraception. The test predicts LH for us to 24-48 hours in advance of your surge, yet sperm can survive for up to 72 hours (3 days). As a result, you may still become pregnant if you test and have intercourse before you discover your surge.

I have not seen any peak fertility days. Why is this? Your LH surge may be too low to be detected, your LH surge may be very rapid, or you may not have ovulated this cycle. This is not unusual but we recommend you see your physician if you do not see a positive result or elevated LH values for 3 consecutive cycles. If you miss a test around your LH surge you may not see an elevated LH value so remember to test twice a day in the morning and in the evening. When you test twice a day you have higher chances not to miss your LH surge.

I've done all the tests as instructed, but I've not yet detected my surge. What should I do? Your body produces LH (Luteinizing Hormone) every day during your cycle and you will always have some amount present in the urine. That is why you will see a test line on most of your tests. This is a healthy sign. Just remember, that the result is considered positive if the test line is at the same intensity or darker than the control line. In order to be sure if the test strip is showing a true positive result, it is important to continue testing after you receive the same intensity lines. The test line may become even darker than the control line or it may become pale again, indicating that the previous test result was a true surge. The positive test color line may vary depending on the individual. While some women can see the test line match the control line prior to their ovulation peak others see test lines a way darker than the control one. For some women LH surge can last a couple of days, while for others it only lasts about 12 hours. Please keep in mind that every cycle is unique. Some women do not ovulate every cycle and will not see an increase in LH levels during these non-ovulatory cycles.

ASSISTANCE

If you have any questions or concerns about the use of this product, please call us at 1-800-684-0872 Monday-Friday 8:00 AM to 5:00 PM EST or contact us by email support@pregmate.com.

VISIT US ONLINE

To learn more, please visit us at www.pregmate.com



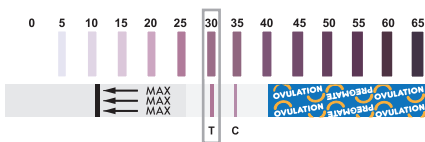
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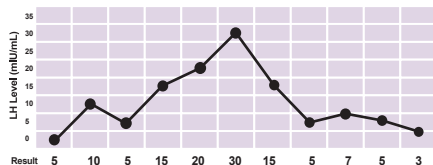
Measuring LH Level

Measuring LH on a numeric basis, in addition to basic ovulation testing, may provide a better understanding of your LH levels and the timing of LH Surge, LH Peak and Ovulation Window.

Compare the Test Line (T) to the lines on the color chart. The numbers on the chart represent the corresponding LH levels.



Graph your result on the Fertility Chart and keep track of your LH curve from month to month.



Note: If the shade of the (T) line is between two colors, record the number in between (e.g., record number 23 if the shade is between colors 20 and 25).

Reading the results

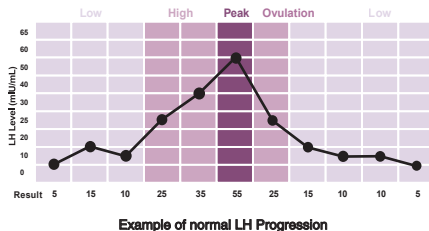
The standard unit of measure for the presence of LH in urine is mIU/mL, which is a milli-international units per milliliter. The typical full range of LH values for women who are NOT PREGNANT can be from as little as <1 to as much as >65 mIU/mL. Most women are experiencing an elevation in LH levels at mIU measurement of 25 mIU/mL.

Low: Line **T** is lighter than line **25** or **T** line is not present.

High: If **T** line is similar to or darker than line **25**, your LH is nearing a surge or surging. Most women at this concentration will ovulate within the next 48 hours.

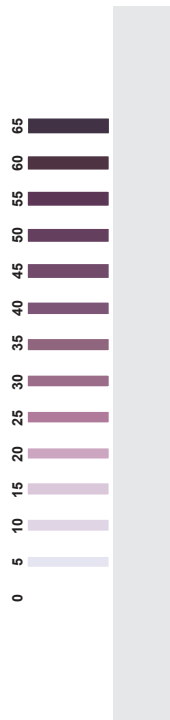
Peak: If **T** line is darker than line **40**, your LH is nearing its highest levels.

Note: Some women have surge levels that are below 25 mIU/mL (Low LH Surge). In that case your LH peak is your darkest test line of all the results.



Color Chart

1. Place the test in the window slot below.
2. Compare the Test Line (T) to the line on the Color Chart.
3. Graph your result on the Fertility Chart.



pregmate®

Information Guide

Ovulation Tests