

Intended Use

The Rapid Response® Ovulation Test Strip is a rapid at home test to help detect ovulation. The test strip is an assay for the qualitative detection of the ovulation hormone, luteinizing hormone (LH), in urine. This test can detect an LH increase (surge), which precedes ovulation. **Read these instructions carefully before using the test.**

How the Test Works

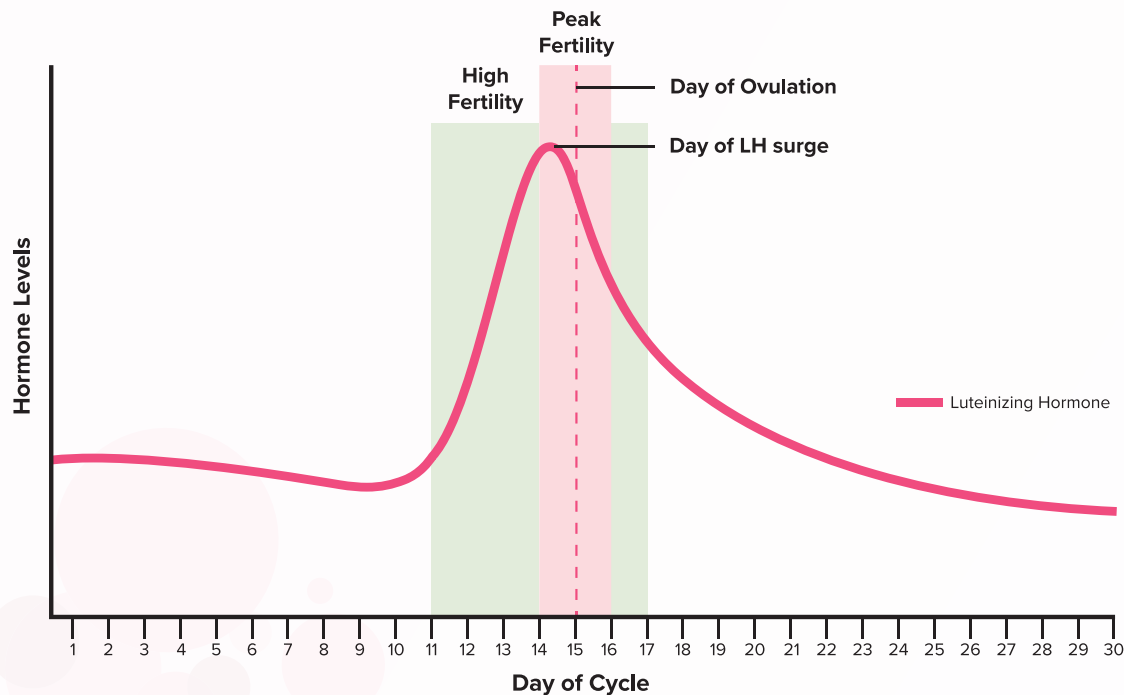
While a woman's body always produces a small amount of luteinizing hormone (LH), there is a sudden increase of this hormone during the middle of the menstrual cycle called the LH surge. The LH surge triggers ovulation, the release of a mature egg from the ovaries. The most fertile time of the menstrual cycle is up to 5 days before expected ovulation to 1 day after ovulation. For most women, ovulation will occur 24-36 hours after the peak of the LH surge. Immediately after ovulation, the egg is capable of being fertilized for around 12-24 hours. This test will produce a positive result when LH is detected in urine samples at or above a concentration of 30 mIU/mL.

Contents of the Box

Provided:	Not provided:
Test Strips (in pouches with desiccant), Product Insert	Urine sample collector, Timer

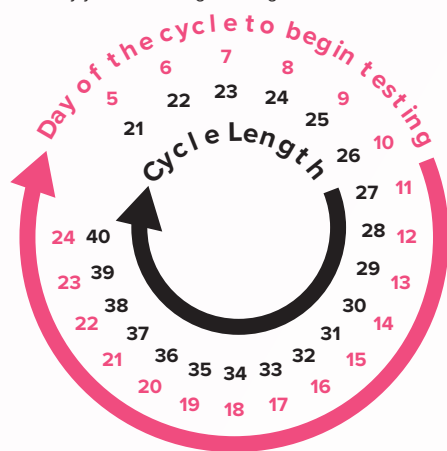
LH Surge & Ovulation

LH Surge and Ovulation



Initial Testing Date

When to start testing depends on the length of your normal menstrual cycle. Day one of your cycle is the first day of your period. The day before your next period is the last day of your menstrual cycle. For average cycle lengths between 28-32 days, the fertile window is likely between days 9-18 with ovulation occurring between days 12-16. Refer to the following chart to determine the day you should begin testing LH level:

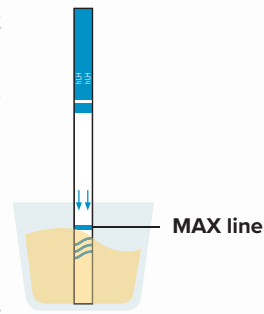


Predicting ovulation is more difficult with irregular menstrual cycles. In this case, calculate the average of the last three cycles, or speak with your doctor.

1 Take the Test

For the best results, test at the same time of the day each day you are testing. Limit liquid intake for 2 hours prior to testing. Unlike pregnancy tests, you should not take the test with the first urine of the day, or during the middle of the night. Collect enough urine in a clean, dry container to submerge the dipping area of the strip.

1. Collect fresh urine in a clean, dry container. You should collect enough to submerge the strip up to the MAX line. If the urine is cloudy, wait a few moments for it to settle.
2. Remove the strip from the pouch, holding it by the coloured end. Do not touch the strip membrane (white area).
3. Holding the strip vertically, submerge the end of the strip with the arrows pointing down. Do not immerse the strip past the MAX line.
4. Take the strip out when the urine has started migrating up the test strip area (after about 10-15 seconds).
5. With the MAX line facing up, lay the strip flat on a clean, dry, non-absorbent surface.



2 Wait for Results

Start the timer for 5 minutes. Wait for the coloured lines to appear. Read the results at 5 minutes, but do not interpret the results after 8 minutes.



3 Reading The Results

POSITIVE

The shade of the Test (T) line is as dark as or darker than the Control (C) line. Ovulation will probably occur within the next 24-36 hours. This is the ideal time to have intercourse if trying to get pregnant.

NEGATIVE

The Test (T) line is not present or is lighter than the Control (C) line. This indicates a low level of LH. No LH surge has been detected, which is a negative result for ovulation.

INVALID

Do not interpret the results if there is no Control (C) line. Discard the test, review the procedure and test again. If you keep getting invalid results, contact us at support@btbx.com.

Performance

Accuracy: The Rapid Response® Ovulation Test Strip detects LH surges with a 98.7% accuracy.
Sensitivity: The Rapid Response® Ovulation Test Strip will show a positive result for LH above concentrations of 30 mIU/mL in urine.

Storage & Stability

Store between 2-30°C (36-86°F) up to the 'use by' or expiration date (indicated by the hourglass symbol on the packaging). Keep sealed tests away from humidity, heat and freezing. Allow the test to reach room temperature before use, leaving it to sit for at least 30 minutes at room temperature if it is being stored refrigerated. Keep in sealed pouch until use. Do not use if the pouch is damaged or not sealed. Use the test immediately after removing it from the pouch.

Limitations

This test is not a method of contraception. This test should not be used during pregnancy, after the onset or menopause, or soon after or during hormone treatment. Not every woman ovulates mid-cycle. If you are not seeing positive results, you may need to start testing earlier and for more days during your next cycle. A low incidence of false results may occur due to several factors including the presence of interfering substances, or procedural errors. Inaccurate results may occur due to some medications or diseases related to hormonal imbalances. In these scenarios or with repeated unexpected results, it is advised to consult a physician. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test.

Warnings

Not for internal use. For *in vitro* diagnostic use. For self-testing at home. Discard expired tests. This is a single use device, do not reuse. Keep out of reach of children. Contains small parts. Do not eat the components of the test. If accidentally swallowed, seek medical advice. Do not touch the test strip membrane to avoid contamination. Do not immerse, soak, or dip the test above the maximum depth mark. Limit exposing the test to humid conditions, as humidity and high temperature may adversely affect results. Use the test immediately after sample collection. Use fresh urine, do not allow urine to sit for a prolonged period at room temperature before using the test. If the urine sample is cloudy, allow it to settle until it is clear. Urine samples may be infectious, use care when handling. Use a clean, dry collection container for each urine sample. Protect the test from contamination. This test is for human urine only. Dispose of test with normal household waste.

Glossary of Symbols

Consult instructions for use	Test per Kit	Catalogue number
Store between 2°C to 30°C	Use by date	Do Not Reuse
<i>In vitro</i> diagnostic medical device	Lot Number	Manufacturer

Contact

If you have questions, reach out to our Technical Support:
support@btbx.com
1-888-339-9964
Monday-Friday 9:00AM-5:30PM EST.

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