



MIDSTREAM OVULATION TESTS

INTENDED USE

The Thyme Ovulation test is a qualitative test used to predict when there is a LH surge, and in turn, when you are likely to ovulate.

For self-testing at home.

For *in-vitro* diagnostic use only, not for internal use.

Do not reuse.

INTRODUCTION

LH (Luteinizing Hormone), present in urine, will increase drastically in the middle of the menstrual cycle. The LH increase triggers ovulation which is when the egg is released periodically from fertile women. WHO experts state that LH testing is a reliable way to detect ovulation. Ovulation will occur after 24-48 hours following a positive test.

PRINCIPLE

When urine is applied to the test device, capillary action carries the sample to migrate along the membrane. When LH in the urine reaches the Test Zone region of the membrane it will form a coloured line. Absence of this coloured line suggests a negative result. To serve as a procedure control, a coloured line will appear at the Control Zone region, if the test has been performed properly. The test detects ovulation with a high degree of certainty. It is a valuable tool in helping achieve pregnancy since it determines the period that the egg and the sperm cells will meet in the best conditions.

Ovulation may be irregular because of various reasons. You therefore cannot presume that ovulation always occurs at the same time after menstruation. Repeat testing in a new menstrual cycle is recommended.

REAGENTS

The test contains anti-LH particles and anti-LH antibodies coated on the membrane.

MATERIALS

Materials provided:

A foil pouch containing a midstream test and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedure. Instructions for use.

Materials required but not provided:

Timer

WARNINGS / PRECAUTIONS

Do not open the foil pouch until you are ready to do the test.
Do not use after the expiry date.
Do not use the test device if the foil pouch has been damaged or opened.
For single use only – do not reuse.
Discard the test device after use.

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 your menstrual cycle before testing. Please refer to the chart below to determine when you should start testing. If your cycle is shorter than 21 days or longer than 38 days, consult a physician. 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. Perform 1 test each day over a 5 day period, or until the LH surge has been detected.

Cycle Chart	Cycle Length	Day of Cycle to Begin Testing
	21 days	day 5
	22 days	day 6
	23 days	day 7
	24 days	day 8
	25 days	day 9
	26 days	day 10
	27 days	day 11
	28 days	day 12
	29 days	day 13
	30 days	day 14
	31 days	day 15
	32 days	day 16
	33 days	day 17
	34 days	day 18
	35 days	day 19
	36 days	day 20
	37 days	day 21
	38 days	day 22
	39 days	day 23
	40 days	day 24

Example: If your cycle is normally twenty-six days, the Cycle Chart indicates testing should begin on day 10. The following calendar shows how to determine day 10.

Sample calendar

1	2	3+ day 1	4	5	6	7
8	9	10	11	12+ day 10	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

3+ = The first day of menstrual bleeding

12# = The day to begin testing (Day 10)

PERFORMANCE & ACCURACY

Unlike pregnancy tests, where the use of first morning urine is recommended, a urine sample taken at any time during the day can be used. For best results collect your urine at the same time each day.

The sensitivity of this test is 25mIU/ml.

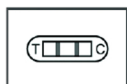
100% correlation with commercially available ovulation tests.

DIRECTIONS FOR USE



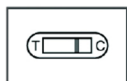
1. Remove the test from the sealed pouch when you are ready to do the test, not before.
2. Hold the test device in one hand. Pull off the cap and expose the absorbent tip.
3. Point the absorbent tip downward into your urine stream for at least 10 seconds to be thoroughly wet. Do not urinate on the result window. (If you prefer, you can urinate into a clean, dry cup or container and perform the test by dipping the absorbent tip of the test into the urine for at least 3 seconds.)
4. Re-cap the test device and lay it down flat with the result window facing up.
5. Wait for the colour lines to appear. The control line (C) indicates that the test is working and the test line (T) indicates a positive result.
6. The complete reaction time of 5 minutes is required.
7. Do not read the test results after more than 5 minutes as it may no longer be accurate due to the composition of the test.

INTERPRETATION OF RESULTS



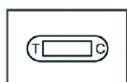
POSITIVE/ LH SURGE

If two colour bands are visible, and the test band is equal to or darker than the control band, 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

Only one colour band appears on the control region, or the test band appears but is lighter than the control band. This means there is no LH surge.



INVALID RESULT

If there are no visible colour bands in the result window, the test is invalid. Proper procedures may not have been followed when performing the test. Repeat with a new test device.

LIMITATIONS

- The test will not work if the test procedures are not followed precisely.
- This test may not be used as a form of birth control.
- Consult a physician if irregular or unusually long cycles are experienced.
- The test is a qualitative screening assay. It is not designed to determine the quantitative concentration of LH.
- The device is only suitable for human urine test.
- Unclean sample or interfering substances in the urine may cause a false result.

QUESTIONS & ANSWERS

There is a big difference between the control lines of two tests. Is this a concern?

No. Variations in the colour of the control band will not affect the test result. It is only effective to compare the colour of the test band to that of the control band of the same test device on the day the test is performed.

Can test results be interpreted after more than five 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 device to avoid confusion.

How long should I continue to perform the test?

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

A pink background colour 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 room. Such variations in physical conditions can cause the vertical streaking and/or the pink-rose background colour but will not affect the test results. As long as the control band appears within 5 minutes the test is working properly.

Do alcohol or common medications affect the test?

No, but you should consult your physician if you are taking any medication.

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 is advised within this time frame.

I am now using the basal body temperature method (BBT).

Does this test replace BBT?

No, the rising in basal body temperature primarily indicates that ovulation has already occurred. This test indicates that ovulation is about to occur.

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

Many factors can affect your ability to become pregnant. Often you may need to use the test kit for 3-4 months. It is advisable to consult your physician after 6 months of not falling pregnant.

Will the amount of liquid I drink affect the results?

We suggest that you limit your fluid intake for about two hours before you take the test as heavy intake of fluids prior to testing will dilute the hormone in your urine.

STORAGE AND STABILITY

Store between 4 – 30 °C, in the sealed pouch, up to the expiry date. Keep away from direct sunlight, moisture and heat. Do not freeze.

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