

LH

One Step Ovulation Test Device (Urine) Package Insert

A rapid, one step test for the qualitative detection of luteinizing hormone (LH) in urine.

For professional *in vitro* diagnostic use only.

INTENDED USE

The LH One Step Ovulation Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation.

SUMMARY

Ovulation is the release of an egg from the ovary. The egg passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH). This is known as the "LH surge" and usually takes place in the middle of the menstrual cycle. LH triggers the release of an egg from the ovary.

The LH One Step Ovulation Test Device (Urine) is a complete system to help you predict the time of ovulation and peak fertility. It is during this fertile time that pregnancy is most likely to occur.

The LH Ovulation Test Device (Urine) detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24-36 hours.

Important: The LH surge and ovulation may not occur in all cycles.

REAGENTS

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

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- Determine the time you will collect your urine. For best results, collect your urine at about the same time each day, for example, between 10:00AM and 8:00PM. Some women have found that their best specimen is after 12 noon. Do not collect your first urine after waking up.
- Reduce your liquid intake approximately 2 hours prior to urine collection.
- Be sure to write down the cycle day, date and time that you collected your urine in the "Test Results Chart".
- You can store your urine for testing later in the day. Your urine can be stored at room temperature for up to 8 hours or in the refrigerator for up to 24 hours. Do not freeze it. For best results, test your urine on the same day that it is collected. If you refrigerate your urine, let it reach room temperature before testing (about 30 minutes). Do not shake the container. If sediment forms at the bottom of the collection container, allow the sediment to settle. Use only urine from the top of the container.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

WHEN TO START TESTING

Determine the Length of Your Menstrual Cycle.

Your Menstrual Cycle Length is the number of days from the first day of your period (menstrual bleeding) to the last day before your next period starts. Think back over the last few months to decide what your usual cycle length has been.

Circle your usual cycle length on the WHEN TO START CHART below. Select the number directly underneath.

Starting the first day of your last period, count ahead the selected number of days on your calendar. This is the day you should begin testing.

WHEN TO START CHART

Circle Your Usual Cycle Length

21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
6	6	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

Count ahead this many days STARTING WITH THE FIRST DAY of your LAST period.

Note: If you are unsure about your cycle length, you may want to use your shortest cycle length when reading the chart. If you do this, you may need to test for more than 5 days.

Example: My usual cycle length is 28 days. My last period started on the third. The "When to Start Chart" shows that I will count ahead 11 days beginning with the third. When I count 11 days ahead on the calendar, I find that I will collect and test my urine starting on the 13th. (See "Sample Calendar" below).

Sample Calendar

Sun.	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.
	1	2	(3)	4	5	6
7	8	9	10	11	12	<13>
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

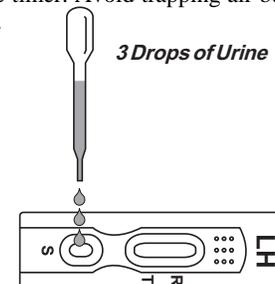
()--First day of your last period

< >--Begin testing with the LH One Step Ovulation Test Device (Urine)

DIRECTIONS FOR USE

Allow the test device, urine specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Determine the day you will begin testing. (See the above section: "WHEN TO START TESTING").
- Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
- Start the timer and wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

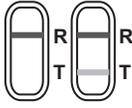


INTERPRETATION OF RESULTS



Positive

POSITIVE: Two lines are visible and the Test Line (T) is the same as or darker than the Reference Line (R). This indicates that you will probably ovulate within 24-36 hours.



Negative

NEGATIVE: Two lines are visible, but the Test Line (T) is lighter than the Reference Line (R), or there is no Test Line. This indicates that no LH surge has been detected and you should continue daily testing.



Invalid

INVALID: Reference Line fails to appear. Insufficient specimen volume or incorrect procedural technique are the most likely reasons for an invalid result. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the Reference Line region (R) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

A positive result means your urine contains the level of LH that would indicate you are beginning to ovulate. You can assume that you will ovulate within 24-36 hours.

A negative result means that no LH surge has been detected and you should continue daily testing.

Not every woman ovulates mid-cycle; therefore, you may not see a positive result during the first 5 days of testing. Continue testing with the LH One Step Ovulation Test Device (Urine).

LIMITATIONS

1. The test works only when the test procedures are precisely followed.
2. Do not reuse the test device.
3. For professional *in vitro* diagnostic use only.
4. This test may not be used as a form of birth control.
5. The test results should not be affected by pain relievers, antibiotics and other common drugs. Medication containing hCG or LH may affect the test and should not be taken while using the LH One Step Ovulation Test Device (Urine). In addition, the test will not work properly if you are pregnant, menopausal, or taking birth control pills.
6. Keep out of the reach of children.

PERFORMANCE CHARACTERISTICS

Laboratory studies have shown that the sensitivity of the LH One Step Ovulation Test Device (Urine) is 40 mIU/mL and the accuracy is 99%.

INTERFERENCE TESTING

The LH One Step Ovulation Test Device (Urine) has been tested with commonly known drugs and hormones including FSH (1,000 mIU/mL), TSH (1,000 μ IU/mL), and hCG (10,000 mIU/mL). At the levels tested, none of these substances interfered with the expected test results.

QUESTIONS AND ANSWERS

1. **Can I use the LH One Step Ovulation Test Device (Urine) to avoid pregnancy?**
No, the test should not be used as a form of birth control.
2. **Do alcohol or common medications affect the test?**
No, but you should consult your physician if you are taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding or pregnancy could affect the results.
3. **What time of the day should I perform the test? Do I need to use first morning urine?**
We do not recommend first morning urine because it is concentrated and may give a false positive result. Any other time of day is suitable. For best results, try to collect your urine at approximately the same time each day.
4. **Will the amount of liquid I drink affect the result?**
Heavy intake of fluids prior to testing will dilute the hormone in your urine. We suggest that you limit your fluid intake for about two hours before you collect your urine.
5. **How long will the line remain visible?**
The test should be read at 5 minutes for best results. A positive (Surge) result will never disappear. The colored line(s) may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second color line because of evaporation from the test region. Therefore, you should not read the result after 10 minutes and discard the test device once you have read the result.
6. **Once I see a positive result, when is the best time to have intercourse?**
Ovulation is likely to occur within 24-36 hours. This is your most fertile time. Sexual intercourse within this time frame is advised.

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

The shift in basal body temperature primarily indicates that ovulation has already occurred. The LH One Step Ovulation Test Device (Urine) indicates that ovulation is about to occur.

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

There are many factors that can affect your ability to become pregnant. It can take normal, healthy couples many months to achieve pregnancy and often you may need to use the test kit for 3-4 months before achieving pregnancy. If pregnancy is not achieved after 3-4 months, you and your partner should consult your physician.

9. **I have had a positive result and had intercourse during these fertile days. I think I may be pregnant. How soon can I find out?**

The pregnancy products can provide you with results as early as the first day you missed your period.

TEST RESULTS CHART

Test	Date	Collection time	Result
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			

REFERENCE

1. Elkind-Hirsch, K; Goldzieher, JW; Gibbons, WE and Besch, PK. *Obstetrics and Gynecology*, 67(3): 450-453, 1986.