



LH One Step Ovulation Test Device (Urine)

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

For in vitro diagnostic use only.

INTENDED USE

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

SUMMARY

Ovulation is the release of an egg from the ovary. The egg then 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) that triggers the release of a ripened egg from the ovary. This "LH surge" usually takes place in the middle of the menstrual cycle.

ATLAS 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.

ATLAS LH Ovulation Test Device (Urine) detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24-48 hours.

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

REAGENTS

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

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°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

URINE ASSAY

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 date, cycle day and time that you collected your urine in the "Test Results Chart" on the back of this instruction.

You can store your urine for later testing 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 a sediment forms at the bottom of the collection container, allow the sediment to settle. Use only urine from the top of the container.

PROCEDURE

Materials Provided

- Test device with disposable dropper sealed in aluminum pouch.
- 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 39 40

06 07 08 09 10 11 12 13 14 15 16 17 18 19
20 21 22 23

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 "Specimen Calendar" below).

Specimen 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			

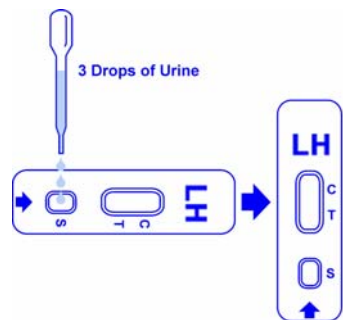
()--First day of your last period

< >--Begin testing with ATLAS 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").
- Bring the pouch to room temperature before opening it. 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 the illustration below.
- Wait for the red line(s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS



POSITIVE: Two lines are visible, and the line in test region (T) is the same color as or darker than the one in the control region (C). It indicates that ovulation will occur within 24-48 hours.



NEGATIVE: If two lines are visible, but the line in the test region (T) is lighter than the color in the control region (C), or if there is no line in the test region (T). It indicates no LH surge has been detected.



INVALID: Control line fails to appear.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. 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 positive result means your urine contains the level of LH that would indicate ovulation will occur within 24-48 hours.

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

Ovulation does not occur at mid-cycle in all woman, therefore, you may not see a positive result during the first 5 days of testing. Continue testing with *ATLAS LH One Step Ovulation Test Device (Urine)*.

LIMITATIONS

1. The test works only when the test procedure is

- precisely followed.
2. Do not reuse the test device.
3. For *in vitro* diagnostic use.
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 *ATLAS LH One Step Ovulation Test Device (Urine)*. In addition, the test will not work properly if you are pregnant, in menopause, or are taking birth control pills.
6. Keep out of the reach of children.

QUESTIONS AND ANSWERS

1. Can I use *ATLAS LH One Step Ovulation Test Device (Urine)* to avoid pregnancy?
No, the test shouldn't 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 medication.
3. 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 color line 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, which prevents complete migration of the test chemicals. Therefore, you should discard the test device once you have read the test.
4. 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 within this time frame is advised.
5. 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. *ATLAS LH One Step Ovulation Test Device (Urine)* indicates that ovulation is about to occur.
6. I have received a positive result and had intercourse during these fertile days. I have not become pregnant. What shall I do?
There are many factors that can affect your ability to become pregnant. Often you may need to use the test kit for 3-4 months before achieving pregnancy. You and your partner should consult your physician if pregnancy is not achieved after 3-4 months.
7. 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?
ATLAS pregnancy products can provide you with results as early as the first day you missed your period.
8. 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, but any other time of day is suitable. For best results, try to collect your urine at approximately the same time each day.

9. 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.

PERFORMANCE CHARACTERISTICS

In laboratory studies, *ATLAS LH One Step Ovulation Test Device (Urine)* has been proven to be 98.7% accurate.

Interference Testing

ATLAS LH One Step Ovulation Test Device (Urine) has been tested with commonly known drugs and hormones including FSH (700 mIU/mL), TSH (500 µIU/mL), and hCG (1000 mIU/mL). At the levels tested, none of these substances interfered with the expected test results.

TEST RESULTS CHART

Test	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.

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