



# ATLAS LH

## One Step

### Ovulation Test Strip (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 Rapid Test Strip (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), which 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 Rapid Test Strip (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 Rapid Test Strip (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 strip 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.
- If the package is not completely sealed do not use the test
- Use the test device immediately after opening it.
- Use a disposable sample container to be discarded after performing the test.
- The pouch contains a Silica Gel pack to absorb

humidity. Do not open the pack. Throw it away with the remainings of the test.

- At the end of the test, wrap every thing you have used in a plastic bag and throw away in the pin. Do not forget to wash your hands properly.
- The remaining sample should be discarded and flushed in the toilet.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test strip 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 strip is stable through the expiration date printed on the sealed pouch. The test strip 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.

#### SPECIMEN STORAGE

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

#### PROCEDURE

##### Material Provided

- Test strips

- Package insert

#### Material 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	06	07	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			

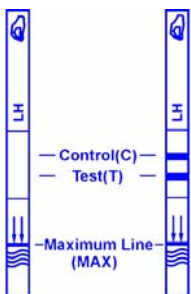
( )--First day of your last period

< >--Begin testing with the ATLAS LH One Step Ovulation Test Strip (Urine).

#### DIRECTION FOR USE

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

1. Determine the day you will begin testing. (See the above section: "WHEN TO START TESTING").
2. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
3. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 5 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.

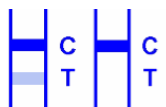


4. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10

### INTERPRETATION OF RESULTS



**POSITIVE:** Two lines are visible, and the line in test region (T) is darker than or the same as the one in the control region (C). It indicates that you will probably ovulate in 24-36 hours.



**NEGATIVE:** If two lines are visible, but the line in the test region (T) is lighter than the one 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 strip. 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 you are beginning to ovulate. You can assume that you will ovulate in 24-48 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 ATLAS LH One Step Ovulation Test Strip (Urine).

### LIMITATIONS

1. The test works only when the test procedures are precisely followed.
2. Do not reuse the test strip.
3. For *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 ATLAS LH One Step Ovulation Test Strip (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 the ATLAS LH One Step Ovulation Test Strip (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 strip 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. The ATLAS LH One Step Ovulation Test Strip (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? The 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, the ATLAS LH One Step Ovulation Test Strip (Urine) has been proven to be 98.7% accurate.

### INTERFERENCE TESTING

The ATLAS LH One Step Ovulation Test Strip (Urine) has been tested with commonly known drugs and hormones including FSH (700 mIU/mL), TSH (500  $\mu$ IU/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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