

AccuMed

One Step Ovulation Test Strip Instruction Insert

Please read all the information in this Insert before performing the test.

The One Step Ovulation Test Strip is an in vitro diagnostic test device intended for the rapid detection of the human Luteinizing Hormones (LH) in urine to predict when there is a LH surge, and in turn, when you are likely to ovulate. You can easily carry out this test yourself.

It is intended for over-the-counter (OTC) use.

For in vitro diagnostic use only.

HOW DOES IT WORK?

The LH (Luteinizing Hormone), which is in the urine of women, will increase dramatically in the middle of the menstrual cycle. The LH increase triggers ovulation which is when the eggs are released periodically from normal 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.

CONTENT OF THE TEST KIT

1. One pouch containing a test strip.
2. Insert with instructions for use.



WHAT ELSE DO YOU NEED?

1. A clean, dry, plastic or glass container to collect the urine.
2. Timer or clock.

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test strip cannot be used more than once.
3. Do not use the test after the expiration date printed on the foil pouch.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.

STORAGE AND STABILITY

1. Store at 39°F to 86°F (4°C to 30°C) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture, and heat.
3. DO NOT FREEZE.
4. You should perform the test soon after opening the pouch. You should keep the test in a dry environment before use.

WHEN TO COLLECT URINE FOR THE TEST?

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 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 days period, or until the LH surge has been detected.

Cycle Chart	Cycle Length		Day of Cycle to Begin Testing	
	Days	Days	Day	Day
	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

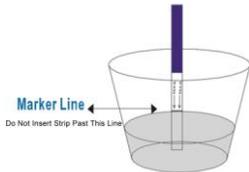
HOW TO COLLECT URINE?

Urine specimens may be collected in any clean, dry, plastic or glass container.

HOW TO DO THE TEST?

1. The test strip and urine have to be at room temperature 59-86°F (15-30°C) for testing.
2. Remove the test strip from the sealed pouch.
3. Immerse the strip into the urine with the arrow pointing towards the urine. Take the strip out after 3 seconds and lay the

strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).
IMPORTANT: Do not allow the urine level to exceed the MAX (marker line), otherwise the test will not perform correctly.
 4. Read results in five minutes. **Do not read results after more than 5 minutes.**

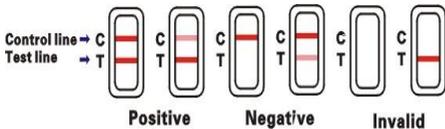


HOW TO READ THE RESULTS

Negative (No LH Surge) :
 Only one color 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.

Positive (LH Surge) :
 If two color bands are visible, and the test band is equal to or darker than the control band, ovulation will probably begin in the next 24-48 hours. If trying to get pregnant, the best time to have intercourse is after 24 but before 48 hours.

Invalid:
 If no band is visible, or there is a visible band only in the test region and not in the control region, the result is invalid. Repeat with a new test kit.



LIMITATIONS

1. The test works only when the test procedures are precisely followed.
2. This test may not be used as a form of birth control.
3. Consult a doctor if irregular or unusually long cycles are experienced.

QUESTIONS & ANSWERS

1. *My cycle length is outside of the range show in the table. How will I know when to start testing?* Start testing 17 days before you expect your next period.
2. *I do not know my usual cycle length. How will I know when to start testing?* If you wish to start using the test before knowing your cycle length, we recommend you start testing on day 10.
3. *What time of day should I take the test?* You may test any time of day, but you should test at approximately the same time each day. You should not have urinated for at least 4 hours before testing.

4. *There is a big difference between the control lines of two tests. Is this a concern?* No. Variations in the color of the control band will not affect the test result. It is only necessary to compare the color of the test band to that of the control band on the same test on the day the test is performed.

5. *Can test results be interpreted after more than five minutes?* No. Test results must be read in 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 5 minutes after taking the test and then discarding the test to avoid confusion.

6. *How long should I continue to perform the test?* At least 5 days or until the LH surge has been detected.

7. *Do alcohol or common medications affect the test?* No, but you should consult your physician if you are taking any medication.

8. *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.

9. *Will the amount of liquid I drink affect the result?* We suggest that you limit your fluid intake for about two hours before you collect your urine. Heavy intake of fluids prior to testing will dilute the hormone in your urine.

PERFORMANCE CHARACTERISTICS

Sensitivity:
 One Step Ovulation Test has a sensitivity of 25 mIU/ml.

Interfering Substances:
 The following potentially interfering substances were added to LH negative and positive specimens and no interference was observed. Acetaminophen, aspirin, ascorbic acid, atropine, caffeine, glucose, hemoglobin, tetracycline, ampicillin, albumin, bilirubin.

MANUFACTURED FOR

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INDEX OF SYMBOLS

	Consult instructions for use		Keep away from sunlight
	In vitro diagnostic medical device		Keep dry
	Store between 4 - 30 °C		Do not reuse