



IVD

Revised 3 Feb. 2006

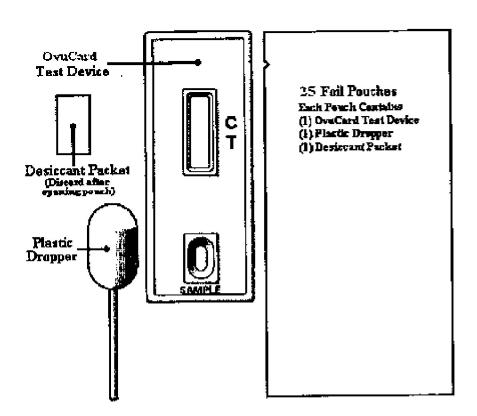
What Is Ovulation?

Ovulation is the release of an egg from your ovaries. You are most likely to become pregnant in the few days around your ovulation. Your body makes a substance called Luteinizing Hormone (LH) that triggers the release of the egg. During most of your menstrual cycle, your body only makes a little LH. But around the middle of your cycle, your body suddenly increases the amount of LH for a few days. This sudden increase is called the "LH surge," and it usually causes you to ovulate. Ovulation usually takes place within 40 hours after the LH surge begins. You should understand that you might not have an LH surge or might not ovulate every menstrual cycle. Even if your menstrual bleeding begins when you expect it to, that does not necessarily mean that you have ovulated. After ovulation, the amount of LH in your body will return to its normal level within 2 days. Unless you get pregnant, this cycle of increase and decrease of LH will repeat again after your menstrual period ends.

OvuCardTM Ovulation Predictor Test is a rapid test used for the detection of Luteinizing Hormone (LH) in urine to predict your time of ovulation.

Kit Contents:

• Your kit contains everything you need to perform 25 tests.



When to Start Testing:





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First you must determine your usual cycle length. To do this, count the number of days from the day your last period (menstrual bleeding) started up to the day before your next period begins. For example, if your last period started on the 1st day of the month and your next period starts on the 31st, your cycle length is 30 days.

Find your usual menstrual cycle length on the left side of the **WHEN TO START CHART**. Look across to find the number of days to count ahead from the first day of your period. This will be the day you begin testing.

If your menstrual cycle varies occasionally, use the average of your last 4 cycles when reading the **WHEN TO START CHART**. If you are unsure about your usual cycle length, use your shortest cycle length from your past 4 cycles when reading the **WHEN TO START CHART**. If you have questions about your cycle length, or if your cycle is not shown on the chart, call your supplier for assistance.

When to Start Chart

If your menstrual cycle	Count ahead this many	If your menstrual cycle	Count ahead this many	
length is this many days	days from the first day of	length is this many days	days from the first day of	
long	your period	long	your period	
21	5	31	14	
22	5	32	15	
23	6	33	16	
24	7	34	17	
25	8	35	18	
26	9	36	19	
27	10	37	20	
28	11	38	21	
29	12	39	22	
30	13	40	23	

Example: "My regular menstrual cycle is 28 days and the first day of my last period started on the 2nd of this month. According to the "When To Start Chart," I should begin testing my urine for an LH surge on the 11th day of my cycle. The 11th day of my cycle this month is the 12th. This means I should begin testing my urine on the 12th of this month."

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

Before You Begin the Test:

• Read the entire pamphlet carefully.







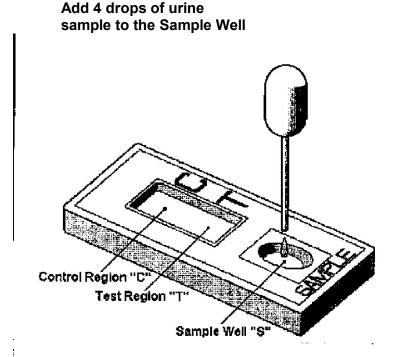
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- Your test can be performed anytime of the day, however, for best results you should try to collect your urine sample for the test about the same time each day. We recommend that you collect your urine sometime between 10 A.M. and 8 P.M., except after you have a large meal or drink a lot of fluids. Remember that in order to obtain the most accurate results; you should always collect your urine at around the same time each day.
- Have a watch or timer available to time the test.
- You should continue testing every day until you detect your LH surge.
- Do not use the test beyond the expiration date printed on the packaging.

Urine Collection:

Collect your urine sample in a collection CUD immediately prior to testing. You only need a small volume of urine, and you will need about 5 minutes to perform the test. If you do not have time to perform the test immediately after collecting your urine, cover and store the urine in your refrigerator. You should not store your urine for longer than 12 hours and von should never freeze it. If your urine has been refrigerated before you are ready to begin testing, you must remove your urine from the refrigerator and let it reach room temperature before you can begin the test. This should take approximately 30 minutes. Do not heat or shake your urine sample.

Test Instructions:



1. Open the foil pouch at the "notch" and remove the test device, the plastic dropper, and the desiccant packet. Discard the





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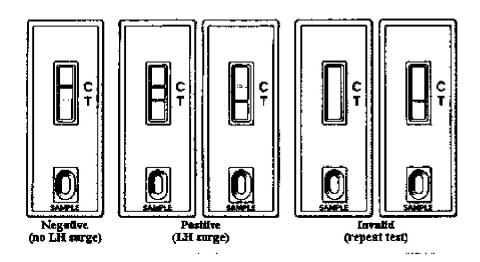
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desiccant packet because it is not used for the test procedure.

- 2. Lay the test device on a clean, level surface. Using the sample pipette provided with the test, add 4 drops of your urine to the Sample Well (SAMPLE). Allow each drop to be absorbed before adding the next.
- 3. Read your test results immediately at 5 minutes. If you wait more than 15 minutes have elapsed you should consider the test results as invalid.

Interpretation of Your Test Result:

- Within 5 minutes, a colored Control Line (C) will appear at the top of the result area to show that the test has been performed correctly.
- When 5 minutes have elapsed, the colored Test Line (T) in the lower section of the result area will provide your test result.



<u>Negative Result</u>: When 5 minutes have passed, if you see that the color of the Test Line (T) is lighter than the color of the Control Line (C), this means that you are not having an LH surge.

<u>Positive Result</u>: When 5 minutes have passed, if you see that the color of the Test Line (T) is the same as the color of the Control Line (C), or darker than the color of the Control Line, it means that you are having an LH surge.

<u>Invalid Result</u>: When 5 minutes have passed, if you do not see any lines, or if you see only a Test Line (T) but do not see a Control Line (C), this means that the test result is invalid. You may not have followed the directions correctly or the test may have deteriorated. You will have to repeat the test using a new OvuCard test.

Understanding Your Test Result:

- If your test result is "**Positive**," it means that you are having an LH surge. No matter how many days your LH surge lasts, you will probably ovulate sometime in the 40 hours after the first day that you detected your LH surge.
- If your test result is "Negative," it means that you are not having an LH surge. You may have started your testing too early in your menstrual cycle. You should continue testing until you detect an LH surge.







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- If you continue to get "Negative" results, you still may have started testing too early, you may have started testing too late in your cycle, or you may not have had an LH surge. It is very important that you understand that you may not have an LH surge every menstrual cycle.
- You can stop testing after you detect your LH surge.

Limitations of the Test:

- You cannot use this test as an aid for contraception (birth control).
- If you are pregnant, in menopause, or taking birth control pills, your test results may not be helpful.

AFTER TESTING:

After test is used, flush the remaining urine sample down the toilet. Discard all components in a waste basket. Do not attempt to

reuse the test device. Questions and Answers:

Q: When is the best time of day to collect my urine and perform the test?

A: You should always perform the test using your "normal" urine. Your first morning urine can be too concentrated, and after a large meal or after drinking a lot of fluids your urine can be too dilute. We recommend that you collect your urine sometime between 10 A.M. and 8 P.M., except after you have a large meal or drink a lot of fluids. In order to obtain the most accurate results, you should always collect your urine at around the same time each day.

Q: Will common drugs affect my test results?

A: Common drugs should not affect your test results. However, if you have been using some kind of birth control method and you have decided to stop using it, please consult with your doctor to determine when you should start testing. If you begin testing too soon after you stop using some birth control methods, such as birth control pills, your may get "false positive" results. That means that your test result may appear to be positive, even though you are not really having an LH surge.

Q: What should I do after I get a positive result?

A: Remember that you will most likely ovulate in the next 40 hours. You should act on this information quickly if you are trying to become pregnant. You may want to check with your doctor for advice that is right for you.

Q: Can I avoid getting pregnant by using the test?

A: NO! The test cannot be used to avoid getting pregnant.

Q: I've used up all the tests in my test kit but I still didn't detect an LH surge. What does this mean?

A: Seven tests are usually enough to detect an LH surge for most women with regular menstrual cycles (cycles that vary by fewer than 3 days). However, if you did not detect an LH surge, you may have started testing too early or too late in your cycle, or you may not have had an LH surge. Call your doctor for advice, or call your supplier for additional information.

Q: Can I use tests from one OvuCard kit along with tests from another OvuCard kit?

A: YES. You can use tests from different OvuCard Ovulation Predictor Test kits as long as you do not use tests after the expiration date printed on the packaging.