

OvuSign[®]

One-Step Home
Ovulation Prediction Test

PBM

For *in vitro* diagnostic use only
Not to be taken internally.

- *Fast: Results in 3 minutes*
- *Simple: Just One Step*
- *Convenient: Works any time of day*
- *Accurate: Over 99% accurate in laboratory studies*

Also from PBM, the maker of the OvuSign[®] One-Step Home Ovulation Prediction Test, is the LifeSign Plus[®] One-Step Home Pregnancy Test, for the early detection of pregnancy.

This test kit contains everything you need to simply and reliably find out when you are likely to next ovulate, which is when your chances of conceiving are greatest. When a woman is about to ovulate (release an egg from an ovary), her brain releases a large amount of luteinizing hormone (LH) which triggers the release of a ripened egg from an ovary. This LH “surge” takes place in the middle of your cycle, and is usually followed by ovulation within 24 -48 hours. The OvuSign[®] One-Step Home Ovulation Prediction Test detects the LH surge in urine, telling you that ovulation is likely to occur in the next 24–48 hours.

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

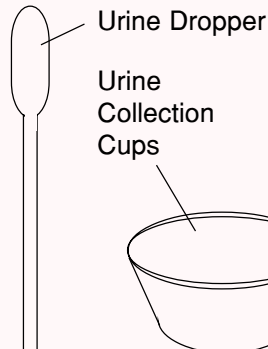
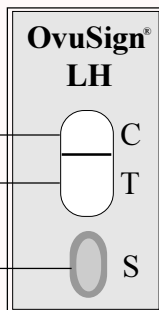
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Test Device

Control Window

Test Window

Sample Well



A SURGE result indicates that the urine contains high levels of LH and you can assume you will ovulate in 24-48 hours from the time of the urine sample. A negative result indicates that no LH surge was detected in the urine.

BEFORE YOU BEGIN

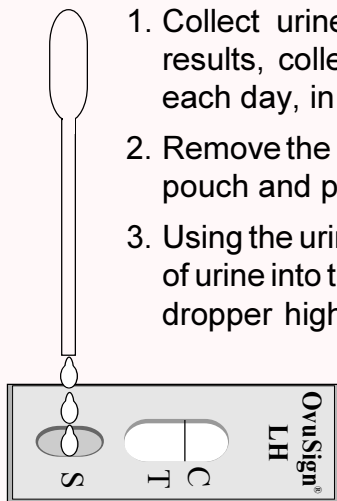
Read all the information in this pamphlet before performing the test. First, make sure you are familiar with the test kit contents shown above. Store at 40–86 F (4–30 C) in the sealed pouch, away from direct sunlight. Do not use after the expiration date stamped on the package.

WHEN TO BEGIN TESTING

Refer to the chart at right to find out when to begin testing. Women with an irregular cycle should use their shortest cycle as a reference. The length of cycle is the number of days from the beginning of one period to the beginning of the next period. If you have an irregular cycle, use your shortest cycle as a reference.

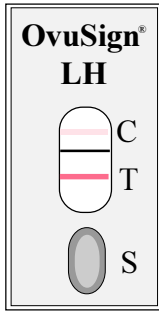
Length of cycle	Begin testing this many days after your last period began
21	5
22	5
23	6
24	7
25	8
26	9
27	10
28	11
29	12
30	13
31	14
32	15
33	16
34	17
35	18
36	19
37	20
38	21
39	22
40	23

INSTRUCTIONS

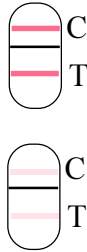


1. Collect urine in the cup provided. For best results, collect urine at about the same time each day, in the afternoon.
2. Remove the Ovusign® test card from the sealed pouch and place it on a flat, dry surface.
3. Using the urine dropper, squeeze 3 large drops of urine into the Sample Well (S). Hold the urine dropper high enough to be able to count the drops. *The test will not work properly if too little urine is added or if urine is spilled into windows C and T.*

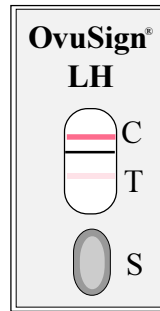
4. Read results in 3–10 minutes.



OR



T same as or darker than C
= SURGE



OR



T lighter than C
= NO SURGE

RESULTS

Wait at least 3 minutes before reading your test.

Positive: If two bands are visible and the one in window T is the same as or darker than the one in C, you will probably ovulate in 24-48 hours.

Negative: If the band in window T is lighter than the one in C or there is no band in the window marked T, no LH surge has been detected.

Invalid: If there is no line visible in window C the test did not work properly and should be repeated with a new OvumSign® test.

HOW TO INTERPRET YOUR TEST RESULT

A positive test result means your urine contains a high level of LH, a hormone that your body makes all of the time but reaches very high levels just before ovulation. You can assume you will ovulate in 24–48 hours, and plan accordingly. The 1–3 days after your LH surge are the most fertile time of your cycle, when you have the best chance of conceiving. A negative result means that no LH surge has been detected and you should continue with daily testing.

LIMITS OF THE TEST

The OvumSign® One -Step Home Ovulation Prediction Test is not reusable. The test instructions must be followed precisely. This test may not be used as a form of birth control. Test results should not be affected by pain relievers, antibiotics and other common drugs. Medications containing hCG or LH may affect the test and should not be taken while using the OvumSign® One-Step Home Ovulation Prediction Test. In addition, the test will not work properly if you are pregnant, in menopause, or are taking birth control pills, or ovulation stimulators (e.g., Clomid®).

SOME COMMON QUESTIONS

Q: What time is best to do the test?

A: Urine should be collected at about the same time every day, if possible. Do not use first morning urine; for best results, use urine collected between 10 am and 8pm.

Q: I didn't use exactly three drops of urine. Will the test still work?

A: One drop more should not affect the result, but we still recommend using exactly three drops of urine. If not enough urine is added the test will not work properly. If you think you may have earned out the test incorrectly, you should do another with a new OvuSign test card.

Q: Does the amount of liquid that I drink affect the test?

A: Try to reduce your liquid intake for about 2 hours before you collect your urine. You don't want to dilute your urine.

Q: How long will the band remain visible?

A: The test should be read within 10 minutes for best results. A positive (SURGE) result will never disappear. The color band may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second color band because of evaporation from the test window which prevents complete migration of the test chemicals. Therefore, you should discard the test card once you have read the result.

Q: How accurate is the test?

A: The accuracy of OvuSign® was demonstrated in a laboratory study in which technicians obtained the correct expected result on a total of 306 (99+%) of 306 blind clinical samples.

Q: I am not sure of my test result What should I do?

A: The OvuSign® test is very easy to read. The test is working properly as long as a pink or purple colored band is visible in the control window, C. The result is positive if the band in the window T is the same as or darker than the band in the window C. Otherwise, no LH surge has been detected.

Q: Can I use OvuSign® as a contraceptive?

A: No. You are most fertile when you ovulate, 24-48 hours after your LH surge, but *you can still become pregnant after ovulation*. It is very important that you do not use this test as a form of birth control.

Q: Can I use OvuSign® to monitor my Clomid® use?

A: No. You should not take Clomid® or other ovulation stimulators and test with OvuSign® at the same time.

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PBM

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