

Some Common Questions & Answers

Q: When can I do the test?

A: As early as the first day you miss your period. First morning urine contains the highest levels of hCG, but the LifeSign® 1 test is sensitive enough to detect hCG in your urine any time of day.

Q: How long does the test take to complete?

A: It usually takes about 1 to 3 minutes. If it takes longer than that, it is likely that you have not collected enough urine. Not using enough urine will cause slow or incomplete reaction. Sometimes this can lead to an incomplete or invalid test result.

Q: I opened the pouch, but I do not have time to conduct the test now. Can I use it later?

A: No. Once you take out the test stick device, you must use it right away. Keeping the test stick after opening the pouch for more than 30 minutes will give an unreliable result. The test stick is very moisture sensitive and will become inactive if it is kept in moist air for any prolonged period.

Q: Can I collect urine in a cup instead of holding the stick in my urine stream?

A: Yes. See the Alternate Procedure on the other side of this leaflet. This method works just as well as holding the stick in your urine stream.

Q: How do I know if I have collected enough urine on the stick?

A: You need to expose the middle portion of the absorbent tip in your urine stream for at least 5 seconds (10 seconds is better). After 1 minute, if you do not see a purple-red color moving up in the test reading window, you probably did not collect enough urine. You need to reexpose the tip in your urine stream right away. Alternatively, you can collect your urine in a clean cup and dip the absorbent tip in the urine mid-length for 5–10 seconds.

If you cannot urinate again, you need a new test kit to test again. The device will not perform correctly once it is exposed to moisture. Once the device is opened and exposed partially to urine, you must finish the test within 30 minutes. If you wait longer than 30 minutes, you should use a new test.

Q: Is the test working properly even if one of the lines is lighter than the other?

A: Yes. Both lines need not be the same shade or intensity. The Test line may be darker or lighter than the Control line. Only one colored line in the Control window indicates a negative result (not pregnant). If no pink-purple line is visible in either window, another LifeSign® 1 test should be performed.

Q: Do I have to wait the full 3 minutes before reading the result?

A: Yes, we recommend that you wait the full 3 minutes before reading the result. However, if your test result clearly shows two reddish lines in just 1 minute, you don't need to wait. If the result in the Test window is not clear, your reading will be more accurate after 3 minutes. Most positive results will appear in 1 minute. Negative results and very early pregnancies require 3 minutes to confirm the test result.

Q: How long will the pinkish-purple line remain visible to show someone?

A: The test should be read within 10 minutes for best results. A positive (pregnant) result will never disappear. The colored line may become darker and a tinted background may appear after several hours. Some negative results may later display a faint second line because of evaporation from the test window, which prevents complete migration of the test chemicals. However, if the result read **within 10 minutes** appears negative (no line in the Test window), you are *not pregnant*.

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

A: The test is working properly as long as a pink-purple colored line is visible in the Control window. The result is positive if there is also a distinct line in the Test window. Otherwise, no hCG has been detected and you can conclude you are *not pregnant*. If there is only a pinkish tint in the window, but no distinct line, the test is invalid and should be repeated. If you are still not sure of your test result, you should repeat the LifeSign® 1 test in a few days with a new test kit.

Q: Can alcohol or medications affect the test?

A: Drinking alcohol will not affect the test. (But it is not healthy for your baby if you get pregnant.) Only medications containing hCG can affect the test result. Other hormone medications, pain relievers, antibiotics, or the contraceptive pill should not affect the test.

Q: How accurate is the test?

A: The accuracy of LifeSign® 1 was demonstrated in a laboratory study in which technicians obtained the correct expected result on a total of 247 (99+%) of 247 blind clinical samples.

Q: Who can I call if I have more questions?

A: You can reach our Customer Service representatives at 1-800-726-2670 Monday through Friday, 9:00 AM to 7:00 PM Eastern Standard Time.

P-5151-B

LifeSign® 1

One-Step Home Pregnancy Test

Self-Test

For *in vitro* diagnostic use.
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*

This test kit contains everything you need to simply and reliably find out whether you are pregnant or not.

When a woman is pregnant, her body makes a hormone called human chorionic gonadotropin (hCG), which can be detected in urine. The LifeSign® 1 One-Step Home Pregnancy Test detects the presence of hCG in urine.

A positive result indicates that the urine contains hCG and you can assume you are pregnant.

A negative result indicates that no hCG was detected in the urine and you can assume you are not pregnant.

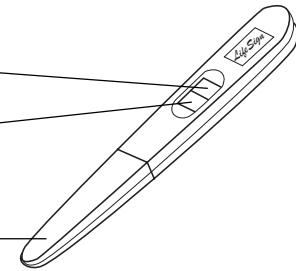
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Individually sealed test device

Control window

Test window

Protective cap

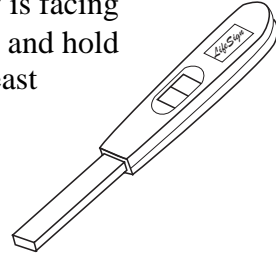


Before you begin

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.

Instructions

1. Open the sealed pouch, remove the LifeSign® *1* test stick, and remove the protective cap. *Once you open the pouch, you should use the test within 30 minutes.*
2. Turn the test stick so that the reading window is facing **away** from you, with the absorbent tip down, and hold the absorbent tip in your urine stream for at least 5 seconds (10 seconds is better).



The test will not work properly if too little urine is absorbed or if urine is spilled into the reading window.

3. Replace the protective cap over the wet absorbent tip and leave the stick on a flat surface with the reading window facing up.
4. Read the result after 3 minutes. While you wait, you will see a pink color moving up the reading window. A pinkish-purple line will form in the Control (upper) window to tell you the test is working correctly.

Alternate Procedure

1. Collect urine into a clean cup. Open the pouch and remove the test as above. Dip the absorbent tip of the stick at least halfway into the urine, for at least 10 seconds.
2. Replace the protective cap over the wet absorbent tip and leave the stick on a flat surface with the reading window facing upward.
3. Read the result after 3 minutes.

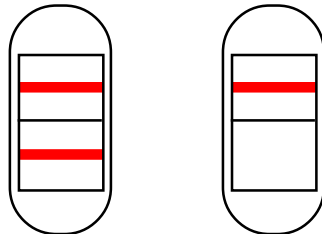
Results

Wait at least 3 minutes before reading your test.

Positive: Two lines, one in each of the reading windows, means you are probably pregnant. *Even if one line is very light, you can assume you are pregnant.* Some positive results may appear in just one minute.

Negative: One line in the Control (upper) window and no line in the Test (lower) window means you are probably not pregnant. Negative results take at least 3 minutes to confirm.

Positive (+)
(Pregnant) Negative (—)
(Not Pregnant)



Invalid: If there are no lines visible in the reading windows, the test did not work properly and should be repeated. A Control line will always appear if the test worked properly.

How To Interpret Your Test Result

A positive test result means your urine contains hCG, a hormone your body makes during pregnancy. You can assume you are pregnant, and should consult your doctor for proper prenatal care and nutrition counseling. A negative result means that no hCG has been detected and you probably are not pregnant. You may want to repeat the LifeSign® *1* test if a week passes and you still have not started menstruating. If the result from this later test is still negative, you are probably not pregnant, but you should see your physician because there could be health-related reasons why you are not menstruating.

Note: Since it can be difficult to know the day you've missed your period, women with an irregular menstrual cycle should use the longest cycle as a reference. If the test is negative and your period does not begin within a few days, you may have miscalculated your cycle and should use a second test.

Limits of the Test

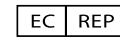
The LifeSign® 1 One-Step Home Pregnancy Test is not reusable. The test instructions must be followed precisely. Test results should not be affected by oral contraceptives, pain relievers, antibiotics and other common drugs. Medications containing the pregnancy hormone hCG may affect the test and should not be taken concurrently.

LifeSign® *1* is highly accurate in detecting pregnancy. In rare instances, however, false results (positive when no pregnancy exists or negative when pregnancy is present) may be observed. You should check with your doctor if you get inconsistent results. Certain health conditions such as an ectopic pregnancy or a cyst in the ovary can cause false results.

The first three months of pregnancy are the most important for your baby. See your doctor immediately for proper prenatal care and nutrition counseling.



P-5151-B 021704BL



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