

PREGNANCY TEST

Instructions

EarlyDETECT™

The earlier, the better.

KIT CONTENTS

This **EarlyDETECT™** Pregnancy Kit contains:

- Pregnancy test wand in a sealed pouch
- Set of instructions

Materials required but not provided:

- Clock or timer

STORAGE & STABILITY

- Store this test kit in its sealed pouch at room temperature (15°–28°C, 59°–82°F).
- Do not use this kit after the expiration date printed on the package.

BEFORE YOU BEGIN

- Read these instructions and understand how to use this test before you begin.
- Do not open the pouch containing the test wand until you are ready to perform the test.
- Verify that the expiration date printed on the package has not passed.

INTENDED USE

The **EarlyDETECT™** Pregnancy Test can be used to detect pregnancy as early as the first day of a missed menstrual period.

When a woman becomes pregnant, her body produces the hormone hCG (human chorionic gonadotropin). The developing placenta begins to secrete this hormone soon after conception, and secretion increases rapidly throughout the first trimester of the pregnancy.

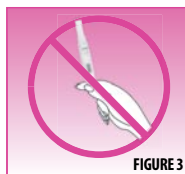
When the test returns a positive result, it is likely that you are pregnant, and you should consult your doctor to discuss your pregnancy and the proper prenatal care for you and your baby.

A negative result indicates the absence of hCG, meaning that you are not likely to be pregnant. If your menstrual cycle is irregular, it can be difficult to know the day you missed your period. Repeat the test with a fresh (unused) test kit. If the result is still negative and you still have not started menstruation, consult your doctor.

In scientific terms, this is a rapid qualitative test with a high sensitivity for detecting the hormone hCG in urine.

INSTRUCTIONS FOR USE

1. Remove the pregnancy test wand from the sealed pouch.
2. Remove the protective cap to expose the absorbent end (as shown in Figure 1).
3. Turn the device so that the absorbent end is pointed down (as shown in Figure 2).
4. Hold the device with the absorbent tip under your urine stream until it is wet— at least six seconds. At this point, it is important not to turn the test wand upside down (see Figure 3).
5. Remove the test wand from your urine stream and replace the protective cap over the wet absorbent end.
6. Continue to hold the test wand with the cap pointing downward. Or you may place the device on a flat surface with the result window showing at the top, but take care not to let the cap point upward.
7. Wait 5 minutes, and then read the results. A positive result may be observed in less than one minute. To verify a negative result, allow the test to run for the full five minutes. Do not interpret your result after ten minutes have passed.



INTERPRETING THE RESULTS

After you have completed the test—whether you are pregnant or not—a Rose-Pink color band will appear in the Control Area (see Figure 4). This indicates that the Pregnancy Test is working properly. Now you can read your result in the test area.

Positive: After the urine has been in the test wand for five minutes, you can conclude that you are pregnant if a Rose-Pink color band appears in the Test Area. Even if a very faint Rose-Pink color band is visible in the Test Area at five



(5) minutes, the Result is Positive. If 2 lines appear, the Result is Positive.

Negative: You can conclude that you are not pregnant if no rose-pink color band appears in the Test Area at five (5) minutes. If 1 line appears, the result is negative.

Invalid: If no lines appear, you may not have applied enough urine to the absorbent end of the test wand; you may not have followed the instructions correctly. Reread the instructions and repeat the test using a new test kit.



LIMITATIONS OF THIS TEST

- The directions must be followed exactly to provide accurate results.
- This test is intended for in vitro (external) use only.
- Do not use the test kit after the expiration date listed on the box.
- Keep this kit out of the reach of children.
- Although the **EarlyDETECT™** Pregnancy Test is highly accurate in detecting pregnancy, a low incidence of false results may occur (positive result when no pregnancy exists or negative result when pregnancy is present). Check with your doctor if you get unexpected or inconsistent test results. Certain health conditions such as ovarian cysts or an ectopic pregnancy (a pregnancy outside the uterus) can cause a false or irregular test result. Testing after delivery can produce a false positive result.
- Each test wand can only be used once. Discard it after use.

QUESTIONS & ANSWERS

Q: How accurate is the **EarlyDETECT™** Pregnancy Test?

A: In both laboratory studies and clinical studies with consumers, the test proved to be over 99% accurate.

Q: How long will my result remain in the test window before it fades away or changes?

A: A positive result is likely to remain unchanged; however, the background may become darker. With a negative result a very faint line may appear in the test window after ten minutes; this color deposit is not a positive result. Do not interpret the test result after 10 minutes.

Q: What makes the lines appear?

A: The test strips located in the wand are coated with proteins that detect hCG in urine. When hCG is present, the test strips react, which causes the rose-pink color band to appear. The control window does not rely on hCG, and a color band appears in this area only when the test has been performed correctly.

Q: Can medication affect the result? Will drinking alcohol or using an oral contraceptive affect the test results?

A: Drinking alcohol will not affect the results. Oral contraceptives, pain killers, antibiotics, or hormone therapies should not affect the test results. Only medicines that contain hCG can produce a false result; these drugs, which are given by injection, include A.P.L.®, Pregnyl®, and Profasi® HP.

Q: Will the amount of liquid I drink affect the result?

A: Excessive fluid intake could dilute your urine, making it difficult to detect the amount of hCG present. Therefore, it is not advisable to change your normal fluid consumption.

Q: What if the test result is positive?

A: A positive result shows that the pregnancy hormone hCG was detected in your urine, and it is very likely that you are pregnant. You should consult your doctor to discuss the pregnancy.

Q: What if the result is negative, but I'm still not sure?

A: If your test shows a negative result (no pregnancy hormone was discovered in your urine), you are not likely to be pregnant. If you are not sure of the result, you may want to re-test your urine within the first week of a missed cycle. If you still have a negative result and your period does not begin, there may be other reasons why you have not menstruated. You should consult your doctor.

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