



hCG

Pregnancy Rapid Test Midstream (Urine) Package Insert

INTENDED USE

The hCG Pregnancy Rapid Test Midstream is a rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy. The test is intended for in vitro diagnostic self-testing.

PRINCIPLE

The hCG Pregnancy Rapid Test Midstream adopts the principles of double antibody sandwich method and immunochromatography to test the human chorionic gonadotropin (hCG) in the urine. The membrane is pre-coated with anti-hCG antibodies in the test region (T) and anti-mouse antibodies in the control region (C). During testing, the urine sample reacts with the colored conjugate (mouse anti-hCG antibody colloidal gold conjugate) which has been pre-coated on the test strip. The mixture then migrates upward on the membrane to react with anti-hCG antibodies in the test region and generate a red line. Presence of the red line indicates a positive result, while its absence indicates a negative result. Regardless of the presence of hCG, as the mixture continues to migrate across the control region, a red line at the region will always appear. The presence of this red line serves as verification for sufficient sample volume and proper flow and as a control for the reagents.

INSTRUCTIONS

Please read all the information in this package insert before performing the test.

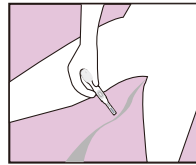
- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 2-30°C or 36-86°F. Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For in vitro diagnostic use. Not to be taken internally.
- Do not open the test foil pouch until you are ready to start the test.

HOW TO USE

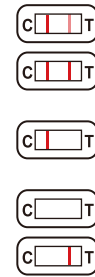
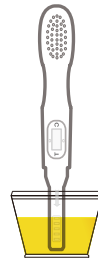
1. Remove the midstream test from the foil pouch and familiarize yourself with the product.
2. Remove the Cap and Hold the midstream test by the capped Thumb Grip with the exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet. See the illustration below.

Note: Do not urinate on the Test and Control windows. If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream test into the urine for at least 10 seconds.

3. After removing the midstream test from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream test on a flat surface with the Test and Control windows facing upwards, and then begin timing.
4. As the test begins to work, you may notice a light red flow moving across the Test and Control windows. **Read the result in 5 minutes.** Do not read the result after 5 minutes.



Or



Positive

Negative

Invalid

HOW TO READ THE RESULTS

POSITIVE:

The presence of two red lines in both the test window (T) and control window (C) means you are probably pregnant. One line may be lighter than the other, they do not have to match.

NEGATIVE:

The presence of one red line in the control window (C) means you are probably not pregnant.

INVALID:

The result is invalid if no red line appears in the control window (C), even if a line appears in the test window (T). You should repeat the test with a new midstream test.

LIMITATIONS

1. This test may produce false negative results. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
2. Certain fertility medications which contain hCG (such as Pregnyl, Profasi, Novarel) can give a false-positive result. Alcohol, oral contraceptives, birth control pills, analgesics (pain killers), antibiotics or hormone therapies that do not contain hCG should not affect the test result.
3. A number of medical conditions other than pregnancy, including, ovarian cyst or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of hCG, which can result in a false positive result.
4. Using the test midstream within 8 weeks of giving birth or having a miscarriage may also cause a positive result. You should ask your doctor for help in interpreting your test result if you have had the experience of pregnancy described above recently.

QUESTIONS & ANSWERS

1. Q: How does the test work?

A: The hCG Pregnancy Rapid Test Midstream (Urine) detects a hormone in your urine that your body produces during pregnancy (hCG-human chorionic gonadotropin). The amount of pregnancy hormone increases as pregnancy progresses.

2. Q: How soon after I suspect that I am pregnant can I take the test?

A: You can test your urine as early as the first day you miss your period. You can perform the test anytime of the day; however, if you are pregnant, first morning urine contains the most pregnancy hormone.

3. Q: Do I have to test with first morning urine?

A: Although you can test at any time of the day, your first morning urine is usually the most concentrated of the day and would have the most hCG in it.

4. Q: How accurate is the test?

A: A multi-center clinical evaluation was conducted comparing the results obtained using the hCG Pregnancy Rapid Test Midstream to another commercially available urine membrane hCG test. The study included 159 urine specimens, and both assays identified 88 negative and 71 positive results. The results demonstrated >99% overall accuracy of the hCG Pregnancy Rapid Test Midstream when compared to the other urine membrane hCG test.

5. Q: How sensitive is the test?

A: The hCG Pregnancy Rapid Test Midstream (Urine) detects hCG in urine at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

6. Q: What should I do if the result shows that I am pregnant?

A: It means that your urine contains hCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.

7. Q: How do I know that the test was run properly?

A: The appearance of a red line in the control window (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.

8. Q: What should I do if the result shows that I am not pregnant?

A: It means that no hCG has been detected in your urine and probably you are not pregnant. If you do not start your period within a week of its due date, repeat the test with a new midstream test. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

You are encouraged to take the following steps to increase your chances for a healthy pregnancy and your baby.

1. Use the Pregnancy Rapid Test Midstream (Urine) to detect pregnancy when your period is late. You can begin better prenatal care as soon as you learn of your pregnancy.
2. If you get a positive result, it is advisable to visit your doctor immediately to begin your prenatal care.
3. Maintain a well-balanced diet, stop smoking, and reduce your intake of alcohol.

AmericanScreening™



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