

Midstream OneStep hCG Test

Catalog # 10110

Instructions

INTENDED USE

The Midstream OneStep hCG Test is a self-performing immunoassay designed for the qualitative determination of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

SUMMARY AND EXPLANATION OF THE TEST

Human chorionic gonadotropin is a glycopeptide hormone produced by the placenta during pregnancy. The appearance and rapid rise in the concentration of hCG in the woman's urine makes it a good pregnancy marker. Usually, the concentration of hCG in urine is at least 25 mIU/ml seven to ten days after conception. The concentration increases steadily and reaches its maximum between the eighth and eleventh week of pregnancy.¹⁻³

The Midstream OneStep Pregnancy Test is a rapid, qualitative test for the determination of human chorionic gonadotropin (hCG) in urine. With this test's high sensitivity, pregnancy can be determined as early as the first day of a woman's missed period.

PRINCIPLE OF THE TEST

The Midstream OneStep hCG Test is comprised of a chromatographic absorbent device and a unique combination of anti-hCG antibodies used to selectively identify hCG in test samples with a high degree of sensitivity. Within five minutes, elevated levels of hCG as low as 25 mIU/ml can be detected.

REAGENTS AND MATERIALS PROVIDED

1. Reaction Stick. Test stick containing coated membrane with monoclonal and polyclonal antibodies and a pad containing monoclonal IgG (antibody) dye conjugate in protein matrix. The test stick is enclosed in a sealed pouch. *Cat. # 10110*

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.

STORAGE AND STABILITY

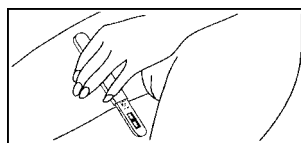
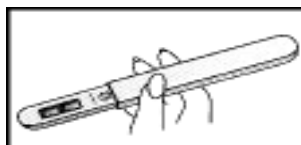
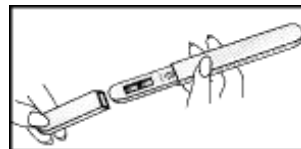
Store the kit below 28°C; do not freeze. Refer to expiration dates for stability.

PROCEDURE NOTES

1. Carefully read the entire instructions before you begin the test. Do not open the foil pouch until you are ready to perform the test.
2. Do not use the test beyond the expiration date printed on the side of the package.

TEST PROCEDURE

1. Remove the Midstream device from its foil wrapper by tearing along the "splice".
2. Take the cap off the test stick (as shown in figure 1).
3. To perform the test, turn the device so that the absorbent windows are pointed downward and facing you (As shown in Figure 2).
4. With the absorbent windows of the test stick downward and facing you, hold the test stick directly into the urine stream for at least six (6) seconds so that adequate urine goes into the absorbent windows (As shown in Figure 3).

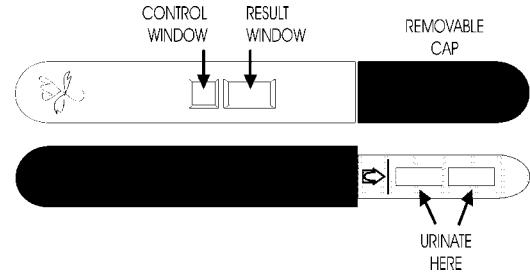


Note: At this point do not invert the test stick. Always keep the end of the test stick with the twin absorbent windows lower than the end with the embossed flower symbol, or at the same height.

5. Remove the test stick from the urine stream and replace the cap over the absorbent windows.
6. Turn the test stick over and either continue to hold the test stick with the cap pointing downward, or lay the device on a flat surface, taking care not to invert the test stick.
7. A pink color should be observed moving across the viewing windows as the test begins to work.

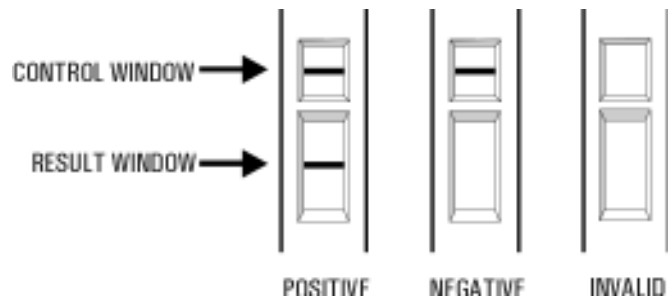
8. Read the result at 5 minutes. A positive result may be observed in less than 1 minute. To verify a negative result, allow the test to run for the full 5 minutes. DO NOT interpret the result after 10 minutes.

VIEWING WINDOWS



INTERPRETATION OF THE RESULTS

After you have completed the test, whether you are pregnant or not, a rose-pink color band will appear in the control window. This indicates that the Midstream OneStep Pregnancy Test is working properly. Now you can read your result in the large result window.



Positive: If there are two rose-pink color bands in the viewing windows; one in the control window and one result window, indicating hCG levels are at or above the sensitivity level of the test.

Negative: If there is only one rose-pink color band that appears in the control window of the viewing windows, indicating the hCG levels are below the sensitivity level of the test.

Invalid: If there is no rose-pink color band in the control window at five minutes, the test result is invalid. Not enough urine may have been applied into the absorbent windows; the instructions may have not been followed correctly or the test stick may have deteriorated.

Re-read the instructions carefully and repeat the test using a new Midstream OneStep hCG Test.

Note: There is no meaning attributed to line color intensity or width.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

The Midstream OneStep hCG Test will detect hCG in urine with a concentration in urine of 25 mIU/ml or greater. This sensitivity level has been confirmed with interval hCG standards (25, 50, 100, 1000, 450,000, and 900,000 mIU/ml) in urine calibrated against the World Health Organization's Third International Standard.

2. Specificity

The glycoprotein LH was tested in hCG-free urine samples at the levels of 50, 100, 300 and 500 mIU/ml. The glycoprotein FSH was tested in hCG-free urine samples at the levels of 50, 100, 500 and 1000 mIU/ml. The glycoprotein TSH was tested in hCG-free urine at levels of 100, 500 and 1,000 μ IU/ml. In all cases the test produced negative results *i.e.* no cross-reactivity was detected.

3. Accuracy

A study was performed by participating physicians and laboratory technicians using a total of 306 positive and negative urine specimens. The testing sites included physician office laboratories and clinical laboratories. The specimens were randomly selected and assayed with 3 lots of the Midstream OneStep hCG Test and a commercially available test according to the respective package inserts. The results are shown in the table below.

Commercially Available Test		
	(+)	(-)
Midstream OneStep hCG Test		
(+)	201	0
(-)	0	105

Four specimens were weakly reactive with both tests and were not included in the data above. These specimen reactions were considered inconclusive: the four specimens were retested by a quantitative RIA method. The results indicated that the samples contained between 20 and 35 mIU/ml hCG activities.

LIMITATIONS OF THE TEST

1. For *in vitro* diagnostic use only (not for internal use).
2. Do not reuse the Test Stick.
3. The test works only when the instructions are precisely followed.
4. Do not use the Test Stick after the expiration date listed on the box.
5. Keep out of reach of children.
6. Although the Midstream *OneStep* Pregnancy Test is highly accurate in detecting pregnancy, a low incidence of false results can occur (positive results 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 result with your test. Testing after delivery can produce a false positive result.

QUESTIONS YOU MAY HAVE ABOUT THE MIDSTREAM ONESTEP PREGNANCY TEST

Can I still use the test if I have collected a urine sample in a collection cup?

Yes, as long as the urine sample is in a clean, dry container and tested right away. Immerse the absorbent windows in the urine for at least 10 seconds and then wait five minutes before you read the results.

How does the test work?

The Midstream *OneStep* Pregnancy Test is uniquely designed to detect a very small amount of the pregnancy hormone hCG (human Chorionic Gonadotropin) in your urine. This particular hormone is produced in increasing amounts during the first trimester of pregnancy.

What do I do if I get a positive result?

If the test is positive, you should consult a doctor to discuss your pregnancy and what steps and precautions you should take next. In addition, you may want to confirm your test result by re-testing with another Midstream *OneStep* Pregnancy Test three days later. Remember, early pregnancy care is very important to ensure the health of you and your baby.

What do I do if I get a negative result?

The colored lines can range from light pink to a dark purple, depending on the concentration of the pregnancy hormone in your urine. However, the depth of the color does not affect your results.

Can Any Medication Affect The Results? Will Drinking Alcohol Or Using An Oral Contraception Affect My Test Results?

Drinking alcohol will not affect the results. Oral contraceptive, pain killers, antibiotics or hormone therapies should not affect the test result. Only medicines which contain hCG (hCG which are given by injection include: A.P.L., Pregnul and Profasi) can produce a false result.

Will The Amount Of Liquid I Drink Affect The Result?

Excessive fluid intake could dilute your urine, causing the amount of hCG present not to be detected properly. It is therefore not advisable to change your normal fluid consumption.

What If The Test Result Is Positive?

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

What If The Result Is Negative, But I Am Still Not Sure?

If your test shows a negative result, no pregnancy hormone (hCG) was detected in your urine. You are not likely to be pregnant or you may have miscalculated your menstrual cycle. 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.