



HCG Early Result Pregnancy Test (Strip)

10 mIU/mL

INTENDED USE

Preview® HCG Early Result Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

Important note regarding negative results:

Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test again a few days after your missed period.

Important note regarding positive results:

If your test result is positive, but think you may not be pregnant, you should check with your doctor.

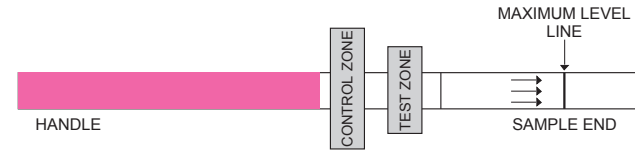
All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

This product is intended for both prescription use and over-the-counter use.

PRINCIPLE

Preview® HCG Early Result Pregnancy Test is a rapid qualitative assay and based on the principle of double antibodies sandwich immunoassay for determination of hCG in urine. When the absorbent end of strip is immersed into a urine sample, the urine will be introduced into a chromatographic membrane. In a reactive sample, the hCG will be captured by β - hCG monoclonal antibody in sample pad. As the conjugate moves forward on the membrane, it will attach to the α - hCG Monoclonal antibody on the test zone ("T"), forming a red line ("T"). Any sample will cause a red line to appear in the control zone ("C"). This line is formed by the binding of the polyclonal antibodies (Anti-mouse IgG) and the

sample-colloidal gold conjugate. Presence of this line indicates that the test has been performed correctly.



REQUIRED MATERIAL

Material Provided

1. One reaction strip
2. One desiccant. It is for storage purpose only.
3. Leaflet with instructions for use.

Material Not Provided

1. For testing at home, urine specimens may be collected in any clean dry glass or plastic container.
2. Timer (watch or clock)

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Single-use device. Do not reuse.
3. Do not use the device beyond expiration date.
4. Do not use the device if the pouch is punctured or not well sealed.
5. Keep out of reach of children.

STORAGE AND STABILITY

1. Store at 39°F~86°F (4°C ~30°C) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. Do not freeze.
4. Please perform the test as soon as possible after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

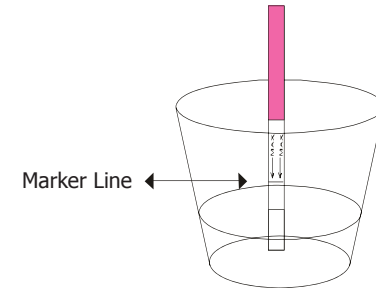
Any urine specimen is appropriate for pregnancy test. But the first morning urine specimen is optimal because of its highest concentration of hCG.

DIRECTIONS FOR USE

1. The test strip and urine should be at room temperature 59°F~86

°F (15°C -30°C) for testing.

2. Remove the test strip from the sealed pouch.
3. Immerse the strip into the urine with the arrow pointing towards the urine. Take the strip out after at least 5 seconds and lay the strip flat on a clean, dry, non-absorbent surface.
IMPORTANT: Do not allow the urine level to exceed the MAX (marker line), otherwise the test will not perform correctly.
4. The complete reaction time of 5 minutes is required. Read results at 5 minutes. Do not read results after more than 10 minutes.



INTERPRETATION OF RESULTS

Negative (Not Pregnant):

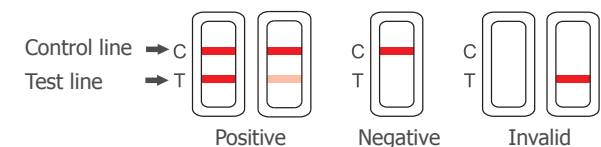
Only one colored line appears in the Control Zone (C). No apparent line in the Test Zone (T). This indicates that no pregnancy has been detected.

Positive (Pregnant):

Distinct colored lines appear in the Control and Test Zones. It indicates that you are pregnant. The color intensity of the test lines may vary since there are different concentrations of hCG hormone in different stages of pregnancy.

Invalid:

No visible colored line at all or there is a visible colored line only in the test region and not in the control region. Repeat with a new test kit. If test still fails, please contact the distributor with the lot number.



NOTE: if the color in the Test Zone is weak, it is recommended that the test

should be repeated in 48 hours.

ADDITIONAL INFORMATION FOR HOME TESTING

What to do when you know the result?

IF THE RESULT IS POSITIVE (TWO LINES)

Consult your physician. He or she should confirm your pregnancy after evaluating all clinical and laboratory findings. Indeed, in certain conditions, the test may give a false positive result. He or she will also give you further information and advice on your pregnancy. See also "Limitations".

IF THE RESULT IS NEGATIVE (ONE LINE)

If you have reasons to believe that you are pregnant (e.g. no menstrual bleeding), you can repeat the test a few days later. If the test is still negative, consult your physician. See also "Limitations".

Expected Results

Negative results are expected in healthy non-pregnant women. Although the hCG levels in normal early pregnant women are variable, Preview® HCG Early Result Pregnancy Test is capable of detecting pregnancy as early as 6 days before the day of missed menses.

Questions and Answers

1. There is much difference between the control lines of two tests. Is this a concern?

No. Variations in the color of the control line will not affect the test result.

2. Can test results be interpreted after more than five minutes?

It is always best to read the results at the 5 minutes in the 10 minutes testing period and then discard the test to avoid confusion. A negative result may change to a false positive within minutes after the end of the 10- minute testing period, which would not be an accurate reading.

3. How accurate is the test?

Preview® HCG Early Result Pregnancy Test is more than 99.0% accurate from the day of the expected period in laboratory studies. The amount of pregnancy hormone increases as pregnancy progresses. In clinical testing with early pregnancy samples, Preview® HCG Early Result Pregnancy Test gave the following results.

Number of days before the expected period	% of samples from pregnant women given a positive test result
-5	68%
-4	89%
-3	97%
-2	98%
-1	>99%
0	>99%

LIMITATIONS

1. As it is with any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
2. Dilute urine samples (i.e. with low specific gravity) may not contain a representative level of hCG, potentially leading to a false negative result. If pregnancy is still suspected, an early morning (first) urine sample should be collected 48 hours later and tested.
3. In very early pregnancy, false negative results may occur when the level of hCG is below the sensitivity level of the test. If pregnancy is suspected, an early morning (first) urine sample should be collected and retested 48 hours later.
4. A significant number of first trimester pregnancies terminate for natural reasons. It is recommended that weakly positive test results should be confirmed by re-testing an early morning (first) urine sample 48 hours later.
5. Elevated levels of hCG can be caused by a number of conditions other than pregnancy, such as trophoblastic disease and some non-trophoblastic neoplasms. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
6. Ectopic pregnancies typically produce lower levels of hCG than normal pregnancies. Consult physicians when ectopic pregnancy is suspected.
7. Any medical procedure which involves hCG, such as fertility treatments, may cause false results. Consult physicians.
8. When the concentration of hCG is very high, it may present a negative result because of hook effect. Diluted sample is necessary in this situation.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Technical Support Number 1-844-337-2743 (8:00 a.m. to 6:00 p.m. PST M-F).

MEANING OF SYMBOLS ON PACKAGE



Keep away from sunlight



Store between 4°C - 30°C (39°F - 86°F)



Keep dry



Do not re-use

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