

hCG Pregnancy Rapid Test (Cassette)

(Serum/Urine)

Please read all the information in the leaflet before performing the test.

INTENDED USE

The Pregnancy One Step Rapid Test is an immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine, serum. The test is used to obtain a visual qualitative result. For in vitro use only.

PRINCIPLE

Human chorionic gonadotropin (hCG) is a hormone, produced by the developing placenta shortly after the conception and secreted into the urine. The pregnancy test contains antibodies which specifically react with this hormone.

When the strip is immersed into a urine specimen, capillary action carries the specimen to migrate along the membrane. When hCG in the sample reaches the Test Zone region of the membrane, it will form a colored line. Absence of this colored line suggests a negative result.

To serve as a procedure control, a colored line will appear at the control zone region, if the test has been performed properly.

REAGENTS

Coated Antibodies

Control region: Goat anti-mouse (IgG) polyclonal antibody

Test region: Mouse monoclonal anti-hCG antibody A

Labeled Antibodies:

Colloidal gold conjugate of monoclonal anti-hCG antibody B

MATERIALS SUPPLIED

1. One pouch containing one cassette device, one pipette dropper and one desiccant. The desiccant is for storage purposes only and is not used in the test procedures.
2. Leaflet with instructions for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers.

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cassette cannot be used more than once.
3. Do not use the test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or is not well sealed.
5. Keep out of the reach of children.
6. Urine specimens may be infectious; Insure proper handling and dispose of all used reaction devices as the local statute.

STORAGE AND STABILITY

1. Store at 2°C to 30°C in the sealed pouch up to the expiration date. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening.

2. Keep away from sunlight, moisture and heat.

3. DO NOT FREEZE.

4. Preferably open the pouch shortly before the test.

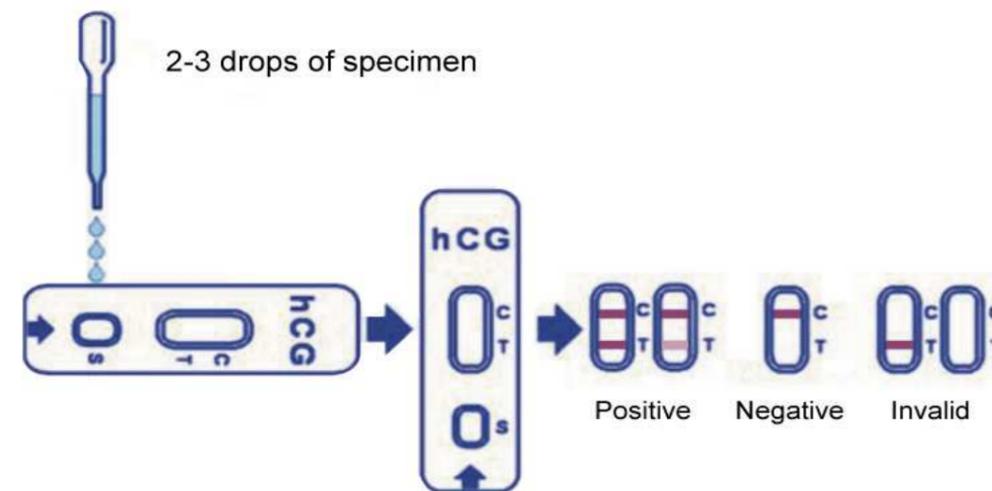
5. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION

1. Any urine specimen is appropriate for pregnancy testing but the first morning urine specimen is optimal because of its highest concentration of HCG.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non- haemolysed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below - 20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with federal, state or local regulations for the transportation of etiologic agents.

TEST PROCEDURE

1. Remove a Testing Device from the foil pouch by tearing at the notch and place it on a level surface.
2. Holding a Sample Dropper vertically, add exactly 2-3 drops of specimen to the sample marked S.
3. Read results in 5 minutes. **Do not read results after more than 5 minutes.**



INTERPRETATION OF RESULTS

Positive

Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). This means you are probably pregnant

Negative

One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). This means you are probably not pregnant.

Invalid

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

NOTE: if the test line is weak, it is recommended that the test be repeated in 48 hours

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. If a urine sample is too dilute (ie, low specific gravity) it may not contain a representative level of hCG. If pregnancy is still suspected, another urine specimen should be collected 48 hours later and tested.
3. Low concentration of hCG in a very early pregnancy can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
4. Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. A normal pregnancy can not be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
6. Sterility treatments, based on hCG, may cause false results. Consult your physician.

QUESTIONS AND ANSWERS

1. 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.

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

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

3. Q: How accurate is the test?

A: A clinical evaluation was conducted comparing the results obtained using the Pregnancy One Step Rapid Test to another commercially available Urine/serum membrane hCG test. The consumer clinical trial included 216 urine specimens: both assays identified 76 positive and 140 negative results. The results demonstrated >99% overall accuracy of the Pregnancy One Step Rapid Test when compared to the other urine membrane hCG test.

4. Q: How sensitive is the test?

A: The Pregnancy One Step Rapid Test detects hCG in urine at a concentration of 25 mIU/ml or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (300 mIU/ml),FSH (1,000 mIU/ml) and TSH (1.000 μ IU/ml) to negative (0 mIU/ml hCG) and positive (25 mIU/ml hCG) specimens showed no cross-reactivity.

5. Q: Which factors may affect the test result?

A: Drugs which contain hCG (such as Pregnyl, Profasi, Pergonal, APL) can give a false positive result. Alcohol, oral contraceptives, painkillers, antibiotics or hormone therapies that do not contain hCG should not affect the test result.

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

A: It means that your specimen 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: Does the result mean anything other than normal pregnancy if it shows that I am pregnant?

A: A number of medical conditions other than pregnancy, including, ovarian cyst or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of hCG.

8. 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.

9. 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 specimen 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.

Please take the following steps to increase your chances for a healthy pregnancy and your baby.

1. Use the Pregnancy One Step Rapid Test 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.