



Proven Medical Testing[®]

Quality Testing, Proven Results

hCG Urine Test Cassette

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

HOW DOES THE TEST WORK?

This test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy. The test utilizes antibodies on the membrane that react with hCG. When the strip contacts with urine, this hCG in urine will move up by capillary action. When hCG reaches the test region, a red line (T) will appear, which is a positive result, otherwise it is a negative result with no line in the test region. There is a control line (C) when the test has been performed properly. This test is for over-the-counter use and for in vitro diagnostic use only.

SPECIMEN COLLECTION

Any urine specimen is appropriate for pregnancy testing but the first morning urine specimen is optimal because of its highest concentration of HCG. The urine specimen must be collected in a clean, dry container either plastic or glass.

MATERIALS SUPPLIED

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

MATERIAL REQUIRED BUT NOT PROVIDED

- Clock or Timer
- Urine specimen collection containers.

WARNINGS AND PRECAUTIONS

- This kit is for external use only. Do not swallow.
- Please read all the information in this leaflet before performing the test.
- Do not use the test kit beyond expiry date.
- Do not open the sealed foil pouch until you are ready to start the test.
- Do not touch the membrane located within the Result Region.
- As with all diagnostic tests, a final clinical diagnosis should not be based on the results of a single test, it should only be made by a physician after all clinical and lab findings have been evaluated.
- Do not reuse the test. Discard it after testing.
- All urine specimens and used cassette should be considered potentially infectious and should avoid contact with skin.
- Do not use the kit if the pouch is punctured or is not well sealed.
- Keep out of the reach of children.

STORAGE AND STABILITY

- Store at 4-30°C or 39-86 °F in the sealed pouch up to the expiration date.
- Keep away from sunlight, moisture and heat.
- DO NOT FREEZE.
- Do not open the inner packaging until ready, it must be used as soon as possible after opening.

TEST PROCEDURE

- Read the entire procedure carefully before performing any tests.
 - Allow test cassette and urine samples to equilibrate to room temperature (20-30 C or 68-86 F) prior to testing.
1. Collect urine as described in section 'specimen collection' of this leaflet.
 2. Remove the cassette from the sealed pouch.
 3. Hold the dropper vertically and transfer 3 full drops of urine to the specimen well of the test cassette.
 4. Wait for colored lines to appear. Interpret the test results between 3-5 minutes. NOTE: Do not read results after 5 minutes.

INTERPRETATION OF RESULTS

*Read results of each test individually. See above illustration.

Positive: Two distinct red lines will appear, one in the test region (T) and another in the control region (C). You can assume that you are pregnant.

Negative: Only one red line appears in the control region (C). No apparent line in the test region (T). You can assume that you are 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). In any event, repeat the test with a new cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

NOTE: If the test line is weak, it is recommended to repeat the test with a new test cassette using the first morning specimen obtained 48-72 hours later. If you suspect you are pregnant, you should see your doctor to confirm the pregnancy.

LIMITATIONS

- If the urine is too diluted or with a very early-stage pregnancy, it can give a negative result. If you get a negative result, and pregnancy is still suspected, another specimen should be obtained at least 48 hours later and tested
- When hCG levels are below the minimum detection level of the test, a false negative result may be obtained. If pregnancy is suspected after a negative result, a first morning urine specimen should be collected 48-72 hours later and tested. If pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis
- A number of conditions other than pregnancy cause elevated levels of hCG and could cause misleading results.
- 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.

QUESTIONS AND ANSWERS

1. Do I have to test with first morning urine? You can perform the test anytime of the day. However, your first morning urine is usually the most concentrated of the day and would have the most hCG in it.
2. If the test result is positive, what do I do? If the test result is positive, you should consult with your doctor and a confirmed pregnancy diagnosis should be made.
3. How do I know that the test was run properly? The appearance of a colored line in the control area (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed
4. If the test result is negative, what do I do? If the test result is negative, you may not be pregnant or the HCG levels are below the cut-off. If pregnancy is still suspected, a first morning urine specimen should be collected 48 to 72 hours later and tested again. It is possible you miscalculated your cycle length.
5. If the test result is invalid, what to do? If the test result is invalid, repeat the test using a new device. Invalid results are usually caused by not enough urine sample applied.