

One Step Pregnancy Test

CE 0123

One Step HCG Urine Pregnancy Test (Strip)

INTENDED USE:

One Step HCG Urine Pregnancy Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in your urine for the early detection of pregnancy.

SUMMARY AND EXPLANATION:

HCG is produced by the placenta during pregnancy, shortly after the embryo attaches to the uterine lining. The further in to the pregnancy you are the higher the levels of HCG in your urine. The concentration of HCG in non-pregnant women is normally 5.0mIU/ml. At the time of the last missed menstrual period, urine HCG levels are about 100mIU/ml with peak levels of 100,000 to 200,000mIU/ml seen at the end of the first trimester.

CONTENTS:

Each pouch contains:

1. One Step HCG Urine Pregnancy Strip Test.
2. Desiccant (Discard - Do not eat).
3. Package insert.

STORAGE AND STABILITY:

The test kit can be stored at room temperature (2 °C to 30 °C) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS:

FOR IN -VITRO DIAGNOSTIC USE ONLY

1. Read directions for use carefully before performing this test.
2. Do not use the test beyond the expiration date on the foil pouch.
3. Each test strip can only be used once; do not re-use the test strips. Discard each test after use.
4. Do not use if the foil pouch is damaged or has been opened.
5. Hold the test strip by the handle only.
6. Once the foil pouch has been opened, the test should be used immediately.
7. Treat urine samples and used tests as if they are potentially infectious. Avoid contact with skin.

TEST PROCEDURE:

1. WHEN CAN I CARRY OUT THE TEST?

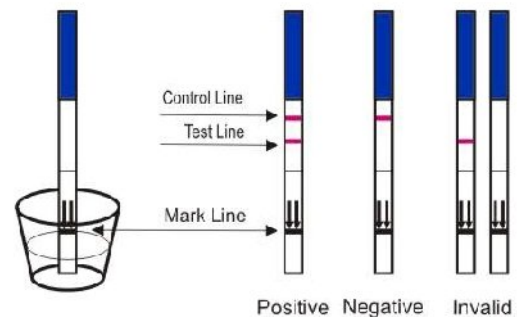
You can take this pregnancy test from the first day you suspect you might be pregnant.

2. SPECIMEN COLLECTION AND HANDLING

A urine specimen must be collected in a clean and dry container. The first morning urine specimen is preferred since it generally contains the highest concentration of HCG; however, urine specimens collected at any time of the day may be used.

TO CARRY OUT THE TEST:

1. Bring the test pouch and urine to room temperature. To begin testing, open the sealed pouch and remove the strip.
2. Place the test strip vertically (straight) into the urine sample for at least 10 seconds, making sure the arrows are pointing downwards. **Do not allow the urine level to go above the MAX (maximum) level line (marked by arrows) on the test strip.**
3. Remove the strip from the urine and place the strip on a clean, dry surface.
4. Read results as coloured bands appear as shown in the diagram. Although positive results may appear as early as 1 minute depending on the concentration of hCG, wait for 5-10 minutes to confirm negative results. It is important that the background is clear before the result is read. Results obtained after 10 minutes may be considered invalid.
5. Discard the test after use.



INTERPRETATION OF RESULTS:

Negative: If one coloured line appears in the control region on the test strip and there is no line in the test region, then this indicates a negative result, no HCG has been detected in the urine. This means you are either not pregnant or you have tested too early. If you are not sure repeat the test in 48 hours.

Positive: If two coloured lines appear on the test strip, one in the test region and one in the control region, then this means there is a strong possibility that you are pregnant — HCG has been detected in your urine. One line may be lighter than the other, they do not have to match and this is still a positive result.

Invalid: If a red line appears in the test region but there is no visible line at all in the control region of the strip then the test is invalid. If no lines appear anywhere on the test strip then the test is also invalid and should be repeated using another test strip.

QUALITY CONTROL:

Built in Quality Control Features:

After addition of the urine sample, coloured bands migrate along the membrane at the leading edge of the dye conjugate and are “removed” from the test strip completely.

When the test is complete, you will see a pink-purple coloured band in the “C” area of the test strip on negative samples and a pink-purple coloured band in the “T” and “C” area on positive samples. The appearance of the CONTROL band indicates that the test strip is performing properly and serves as a procedural control.

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PERFORMANCE CHARACTERISTICS:

ACCURACY

Comparison studies on the **One Step HCG Urine Pregnancy Test** with a legally marketed device were performed in-house and in a clinical reference laboratory. Positive and negative results were compared and the correlation was >99.5%.

PRINCIPLE:

The HCG assay is a rapid one-step test, based on an immunochromatographic technology. A membrane with an absorbent pad overlapping a strip of fibre glass paper that is impregnated with a lyophilized colloidal conjugate of gold particles and monoclonal solid phase antibodies to HCG. Other absorbent pads at the end of the assay absorb excess sample fluid. The urine sample is introduced into the device, and proceeds through the absorbent pad, then laterally onto a chromatographic membrane. As it contacts the membrane, the sample dissolves the lyophilized conjugate. In a reactive sample, the HCG antigen will attach to the antibodies in the colloidal solution. As the conjugate moves forward on the membrane, anti-HCG monoclonal antibody affixed on the test zone ("T") will bind the HCG-gold conjugate complex, forming a pink line ("T"). All samples will cause a pink colored line to appear in the control zone ("C").

This line is formed by the binding of the polyclonal antibodies (Anti-mouse IgG) affixed onto the control zone to the sample-colloidal gold conjugate. Presence of this line indicates that the test has been carried out correctly. All Fastest One Step HCG Urine Pregnancy Tests will display positive results with specimens containing HCG at the level close to or greater than 10mIU/ml or close to or greater than 25mIU/ml depending on which test you have purchased.

REAGENTS:

One Step HCG Urine Pregnancy Test strip per foil pouch.

Ingredients: Test device comprised colloidal gold coated with anti β -HCG antibody; NC membrane coated with mouse anti α -HCG antibody and rabbit anti mouse IgG.

LIMITATION OF THE PROCEDURE:

1. Alcohol may interfere with the test result. It is not recommended to use the test after drinking alcohol.
2. If you test too early HCG levels may still be low and so can give a negative result. In this case, another urine specimen should be obtained at least 48 hours later and tested.
3. HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion or therapeutic abortion.
4. In cases where very high levels of HCG are present (>500,000mIU/ml) a false negative result can occur due to a "Prozone" effect. If pregnancy is still suspected, simply dilute specimen 1:1 with deionized water and retest.
5. 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, a first morning urine sample should be obtained and retested 48 hours later.
6. As is true with any diagnostic procedure, the user should evaluate data obtained by the use of this kit in light of other clinical information and consult their doctor for the final diagnosis of pregnancy before making any decision of medical relevance.

INTERPRETATION OF THE SYMBOLS:

LOT

20090101 - Symbol for "batch code"



2009-01-01 - Symbol for "Use by"