

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.

TEST PROCEDURE:

1. WHEN CAN I CARRY OUT THE TEST?

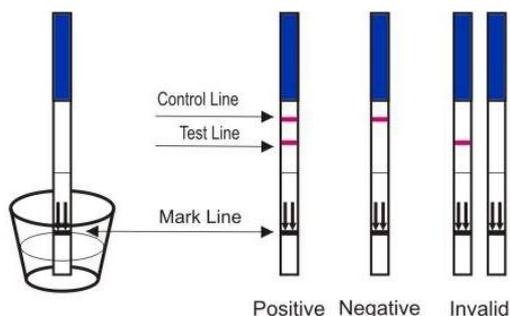
You can take this pregnancy test from the first day you suspect you might be pregnant.

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

3. 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. Wait for coloured bands to appear. Depending on the concentration of HCG in the urine specimen, positive results may be observed in as short as 40 seconds. However, to confirm a negative result, the complete reaction time of 5 minutes is required. Do not read results after 30 minutes.
5. Discard the test after use.



4. 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.

5. 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.

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%.

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.