

One Step HCG Test Strip Instruction Insert

Please read all the information in this Insert before performing the test.

One Step HCG Test Strip is an in vitro diagnostic home use test device intended for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. You can easily carry out yourself.

It is intended for self-testing use.

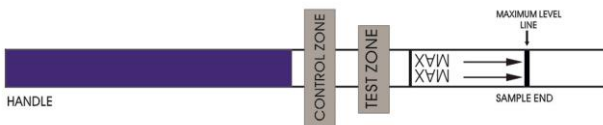
For in vitro diagnostic use only.

HOW DOES IT WORK ?

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

When the sample end of the test is dipped in the urine specimen, the urine specimen is applied to the strip and migrates along the strip. 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.

A colored line will appear at the Control Zone region if the test has been performed properly.



CONTENT OF THE TEST KIT

1. One pouch containing a reaction strip.
2. Leaflet with instructions for use.

WHAT ELSE DO YOU NEED ?

A clean, dry, plastic or glass container to collect the urine.
Timer or clock.

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test strip cannot be used more than once.
3. Do not use the test past the expiration date printed on the foil pouch.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.

STORAGE AND STABILITY

1. Store at 39°F to 86°F (4°C to 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. You should perform the test soon after opening the pouch. You should keep the test in a dry environment before use.

WHEN TO COLLECT URINE FOR THE TEST ?

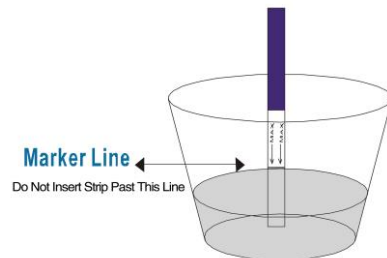
For many women, HCG may be detectable with this test by the day after the missed period. Any urine specimen is appropriate for Pregnancy Testing but the first morning urine specimen is optimal because of its highest concentration of HCG.

HOW TO COLLECT URINE?

Urine specimens may be collected in any clean, dry, plastic or glass container.

HOW TO DO THE TEST?

1. The test strip and urine have to be at room temperature 59-86°F (15-30°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 5 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).
IMPORTANT: Do not allow the urine level to exceed the MAX (marker line), otherwise the test will not perform correctly.
4. Read results in five minutes. Positive results may sometimes appear as early as one minute but you should wait the full 5 minutes before determining a negative result. **Do not read results after more than 5 minutes.**



HOW TO READ THE RESULTS?

Negative (not pregnant) :

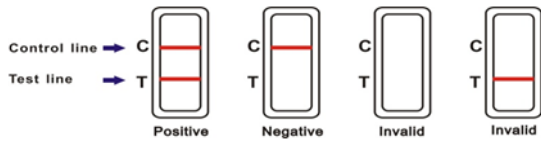
Only one color band appears, in the Control Zone. No apparent band on the Test Zone. This indicates that no pregnancy has been detected.

Positive (pregnant) :

Distinct color bands appear in the Control and Test Zones. It indicates that you are pregnant.

Invalid:

No visible band at all, or there is a visible band only in the test region and not in the control region. Repeat with a new test kit.



NOTE: if the color in the Test Zone is weak, it is recommended that the test be repeated in 48 hours, or if the test shows negative but you suspect you may still be pregnant, the test may be repeated after a few days.

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. In some rare situations the test may give a false positive result. He or she will also give you further information and advice on your pregnancy. See also "Understanding test results".

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 "Understanding test results".

UNDERSTANDING TEST RESULTS

1. 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.
2. 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.
3. Any treatment with hCG may cause false results.

EXPECTED RESULTS

Although the hCG levels in normal early pregnant women are variable, One Step HCG Test is generally capable of detecting pregnancy as early as 1 day after the first missed menses.

QUESTIONS & 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 band will not affect the test result.

2. *Can test results be interpreted after more than five minutes?* No. Test results must be read in 5 minutes. A negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading. It is always best to read the results at the 5 minute testing period and then discard the test to avoid confusion.

PERFORMANCE CHARACTERISTICS

Sensitivity:

One Step HCG Test has a sensitivity of 25 mIU/ml.

Interfering Substances:

The following potentially interfering substances were added to hCG negative and positive specimens, no interferences were observed. Acetaminophen, aspirin, ascorbic acid, atropine, caffeine, glucose, hemoglobin, tetracycline, ampicillin, albumin, bilirubin.

Stability after first opening:

The results of the package opened stability studies show that the products quality was stable and valid within 1.5 hours. Given variations in temperature and humidity that may occur, we suggest to use the test immediately after opening.

MANUFACTURED BY

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INDEX OF SYMBOLS

	Consult instructions for use		Keep away from sunlight
	In vitro diagnostic medical device		Keep dry
	Store between 4 ~ 30 °C		Do not reuse

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