

eve™

Urine Pregnancy Test Strip

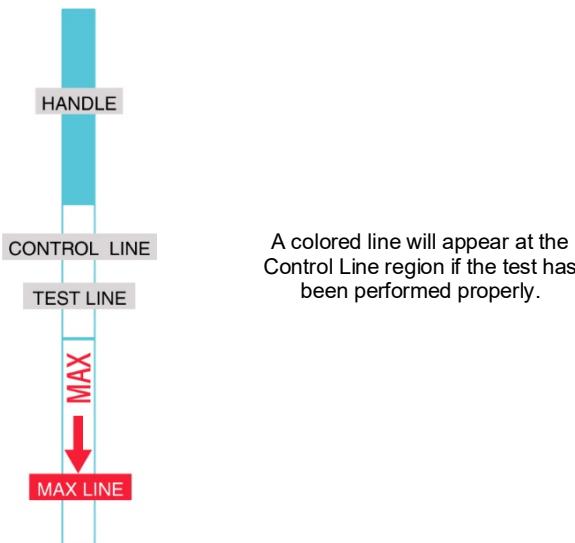
Important: Please read all the information in this insert before performing the test.

eve™ Urine Pregnancy HCG Test Strip is an in-vitro home-use diagnostic test device intended for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid the early detection of pregnancy.

Intended for over-the-counter (OTC) use. For in-vitro diagnostic use only. Not to be taken internally.

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 react specifically with this hormone. When the test strip is dipped in the urine specimen, the urine specimen is applied and migrated along the strip. When hCG in the sample reaches the "Test Line" region of the membrane, it will form a colored line. Absence of this colored line suggests a negative result.



CONTENTS OF TEST KIT

1. Ten 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 intended for external use only. Do not swallow.
2. Discard after one use. The test strip cannot be used more than once.
3. Do not use the test past the expiration date printed on the package.
4. Do not use the kit if the package is punctured or not well sealed.

STORAGE AND STABILITY

1. DO NOT FREEZE.
2. Store at 39°F to 86°F (4°C to 30°C) in a sealed pouch up to the expiration date.
3. Keep away from direct sunlight, moisture and heat.
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?

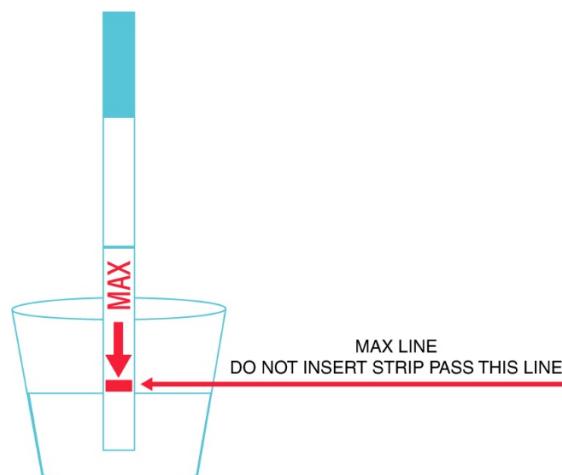
For many women, HCG may be detectable with this test the first day after the missed period. Any urine specimen is appropriate for pregnancy testing but the first morning urine specimen is optimal because of its highest concentration of HCG.

HOW TO COLLECT URINE?

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

INSTRUCTIONS

1. The test strip and urine should be used at a room temperature between 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 down towards the urine. Take the strip out after 3 seconds. Lay the strip flat on a clean, dry, and non-absorbent surface.
- 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 appear as early as one minute, but you should wait for the full 5 minutes before determining a result. **Do not read results after more than 5 minutes.**
5. Keep out of the reach of children.



HOW TO READ THE RESULTS?

Negative (Not Pregnant):

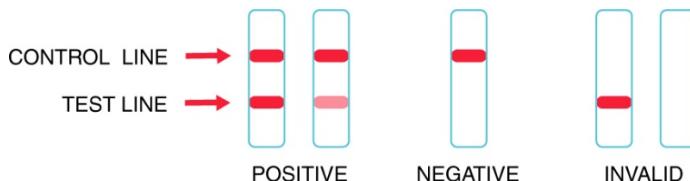
Only one-color band appears, in the "Control Line". No apparent band on the Test Line. This indicates that no pregnancy has been detected.

Positive (Pregnant):

Distinct color bands appear, even if faintly, in the Control and Test Lines. 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 strip.



NOTE: If the color in the Test Line is faint, 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 or false negative. He or she will also give you further information and advise on your condition. Also see "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.

Also see "Understanding test results".

UNDERSTANDING TEST RESULTS

1. If a urine sample is too dilute (i.e. 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 very early pregnancy stage 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 pregnant women in early stage are varied, eve™ Urine Pregnancy HCG Test is generally capable of detecting pregnancy as early as one 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 mark and then discard the test to avoid confusion.

PERFORMANCE CHARACTERISTICS

Sensitivity:

eve™ Urine Pregnancy 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.

DISTRIBUTED 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 39°F to 86°F		Do not reuse

