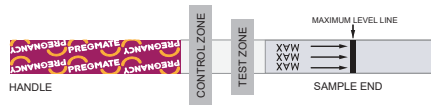


Please read all the information in this insert before performing the test.

Pregmate Pregnancy Test is an in vitro diagnostic home use test device intended for the rapid detection of Human Chorionic Gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use. For in vitro diagnostic home use only.

HOW DOES IT WORK?

Human Chorionic Gonadotropin (hCG) is a hormone produced by the developing placenta and secreted into the urine. The test contains antibodies which specifically react with this hormone. When the sample end of the test is dipped into 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

One pouch containing a reagent strip and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures. Leaflet with instructions for use.

WHAT ELSE DO YOU NEED?

A clean, dry, plastic or glass container to collect the urine. Timer (watch, clock or smartphone).

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, heat.
3. DO NOT FREEZE.
4. You should perform the test soon after opening the pouch. You should keep the test in a dry place 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. However, the first morning urine is preferred because of its highest concentration of hCG.

HOW TO COLLECT THE URINE SAMPLE?

Urine 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 5 minutes. Positive results may sometimes appear as early as one minute, however, you should wait the full 5 minutes before determining a negative result. Do not read results after more than 5 minutes.

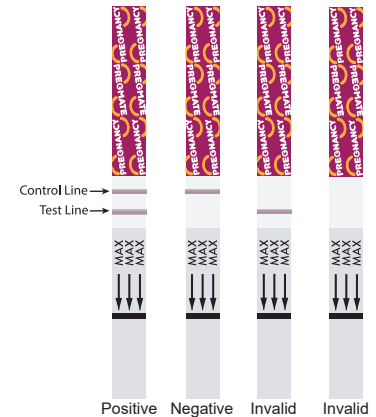


HOW TO READ THE RESULTS?

Negative (not pregnant): Only one-color band appears in the Control Zone. No apparent band in 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 Zone and not in the Control Zone. Repeat with a new test kit.



NOTE: If the color in the Test Zone is very faint, it is recommended to repeat the test in 48 hours or if the test shows a negative result, but you suspect that you may be pregnant, repeat the test after a few days.

WHAT TO DO WHEN YOU KNOW THE RESULT

IF THE RESULT IS POSITIVE (TWO LINES)

Consult your physician to confirm your pregnancy after evaluating all clinical and laboratory findings. In some rare conditions the test may give a false positive result. Your physician will give you further information and advise you 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 diluted (e.g., low specific gravity) it may not contain hCG up to the cut-off level. If pregnancy is still suspected, another test should be performed 48 hours later.
2. Low concentration of hCG in a very early pregnancy can give a negative result. In this case another test should be performed 48 hours later.
3. Any treatments based on hCG may cause false results.

EXPECTED RESULTS

Although hCG levels in a normal early pregnancy are variable, Pregmate Pregnancy Test can detect pregnancy as early as 1 day after the missed period.

QUESTIONS AND ANSWERS

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.

Can test results be interpreted after more than 5 minutes?

No. Test results must be read at 5 minutes. Though a positive result should not change for several days, 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.

ASSISTANCE

If you have any questions or concerns about the use of this product, please call us at 1-800-684-0872 Monday-Friday 8:00 AM to 5:00 PM EST or contact us by email support@pregmate.com.

STABILITY

Real time studies have been conducted by 3 lots of the corresponding pregnancy test strip. The results demonstrate that Pregmate pregnancy test strip unopened (shelf-life) stability is 36 month at 39-86° F (4-30° C).

MANUFACTURED FOR

Pregmate LLC
2268 Anchor Ct
Fort Lauderdale FL 33312 USA

VISIT US ONLINE

To learn more, please visit us at www.pregmate.com



pregmate[®]

Information Guide

**Pregnancy
Test**