

Pregnancy Test Strip

User Manual

CAT.#: PMS1-S



INTENDED USE

Premom Pregnancy Test Strip is a rapid pregnancy test, which you can easily perform at home. It detects the presence of human chorionic gonadotropin (hCG), which appears in urine very early during pregnancy.

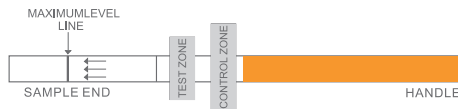
For over-the-counter use only. For external use only.

HOW DOES IT WORK ?

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

When the strip is immersed into a urine specimen, capillary action carries the specimen to migrate along the membrane. When hCG in the sample reaches the Test Zone region of the membrane, it will form a Rosy Pink line. Absence of this Test Line suggests a negative result.

To serve as a procedure control, a colored line will appear at the Control Zone region if the test has been performed properly.



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 kit beyond the expiration date.
4. Do not use the kit if the test pouch is punctured or not fully sealed.
5. Keep out of the reach of children.

STORAGE AND STABILITY

1. Store at 39°F to 86°F (4 °C ~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. The test should be used immediately after opening.

WHEN TO COLLECT URINE FOR THE TEST?

Any urine specimen is appropriate for pregnancy testing. However, the first morning urine specimen is preferred because of its highest concentration of HCG. Do not test this product with fluids other than urine.

HOW TO COLLECT THE URINE SAMPLE?

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

CONTENT OF THE TEST KIT

1. One pouch containing a test strip and a desiccant.

The desiccant is for storage purposes only and is not used in the test procedures.

2. Instruction Manual.

WHAT ELSE DO YOU NEED?

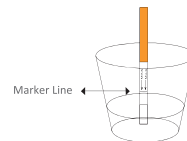
1. A clean, dry, plastic or glass container to collect the urine.
2. Timer (watch, clock or smartphone).

HOW TO PERFORM THE TEST?

1. The test strip and urine have to be at room temperature (15-30°C) for testing.
2. Remove the test strip from the sealed pouch.
3. Dip the white absorbent tip of the test into the urine up to the black "MAX" line and keep the tip in urine until dye rises into the results window. (Est Time:5-10 seconds)

4. Lay the test strip flat on a clean, dry, and non-absorbent surface.

5. Read the result between 3 and 5 minutes after immersion. Do not read results after more than 5 minutes.



HOW TO READ THE RESULTS?

Negative (not pregnant) :

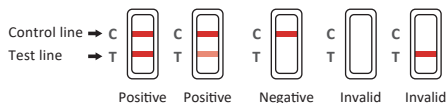
Only one color band appears in the Control Zone and no Rosy Pink band on the Test Zone. This indicates that no pregnancy has been detected.

Positive (pregnant) :

Distinct color bands appear in the Control and Test Zones. It indicates that you are pregnant. The color intensity of the test bands may vary since different stages of pregnancy have different concentrations of hCG hormone.

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. If the test still fails, please contact us for assistance.



NOTE: If the color in the Test Zone is very faint, it is recommended to repeat the test two days later.

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 certain conditions, the test may give a false positive result, and your physician will also give you further information and advise you on your pregnancy.

See also "Limitations" .

IF THE RESULT IS NEGATIVE (ONE LINE)

If you have reasons to believe that you are pregnant (e.g. your period is late), you can repeat the test two days later. If the test is still negative, consult your physician.

See also "Limitations" .

LIMITATIONS

1. Like any other diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.

2. If a urine sample is too dilute (e.g. low specific gravity) it may not contain hCG up to the cutoff level. If pregnancy is still suspected, another urine specimen should be collected 48 hours later and tested.

3. Low concentration of hCG in a very early pregnancy can give a negative result. In this case, another urine specimen should be obtained at least 48 hours later and tested.

4. Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine specimen should not be used alone to diagnose pregnancy, unless these conditions have been ruled out.

5. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.

6. Sterility treatments, based on hCG, may cause false results. Consult your physician on how to do test properly if you are taking any hormone medication.

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 between 3 and 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 between 3 and 5 minutes and then discard the test to avoid confusion.

3. A pink background color and vertical streaking appeared in the result area during the testing period. Is this a concern?







No. Each urine sample will vary in its chemical makeup, as will the humidity of the air in the testing chamber (room). Such variations in physical conditions can cause the vertical streaking and/or the pink-rose background color but will not affect the test results. As long as the control band appears within 3 to 5 minutes, the test is working properly.

If you have any questions, please call us toll-free at **1-855-822-6999 (Monday-Friday 9:00 a.m. - 5:00 p.m. Central Time)**. Our professional staff will be happy to assist you.

To learn more, please visit us at

www.premom.com

MEANING OF SYMBOLS ON PACKAGE

-  Keep away from sunlight
-  Store between 39°F - 86°F (4°C - 30°C)
-  Keep dry
-  Do not re-use
-  For *in vitro* diagnostic use
-  Consult instructions for use

CLIA WAIVED

www.premom.com

Questions or comments?
Please call toll-free:

1-855-822-6999 M-F 9 a.m.-5 p.m. CST

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