

Pregnancy Test

User Manual

CAT.#: PMS1-S

prem^{om}

Please read the full instructions before performing the test.

INTENDED USE

The Premom Pregnancy Test is an *in vitro* diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

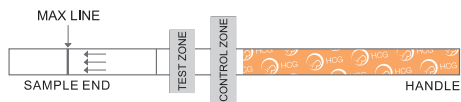
For *in vitro* diagnostic use.

It is intended for over-the-counter use.

ABOUT THE TEST

Human chorionic gonadotropin (hCG) is a hormone produced by the developing placenta shortly after conception and secreted into urine. The pregnancy test contains antibodies that specifically react with this hormone. When the strip is immersed in a urine sample, capillary action carries the specimen to migrate along the membrane. When hCG in the sample reaches the Test Zone of the membrane, a colored line will form, indicating a positive result. The absence of this colored line suggests a negative result.

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



PRECAUTIONS

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

STORAGE AND STABILITY

1. Store the test in the sealed pouch at a temperature between 39°F to 86°F (4°C to 30°C) until the expiration date. If the test has been stored refrigerated, allow it to warm to room temperature before performing the test.
2. The test should be used immediately after opening the sealed pouch.
3. Keep away from sunlight, moisture and heat.
4. Do not freeze the test.

COLLECTION AND STORAGE OF SPECIMENS

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.

HOW TO COLLECT THE URINE SAMPLE

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

CONTENTS OF THE TEST KIT

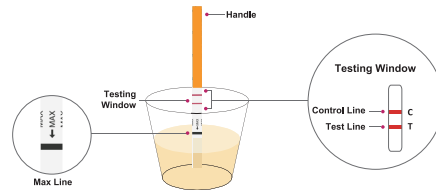
1. One pouch containing a test strip and a desiccant. The desiccant is for storage purposes only and is not used in the test.
2. User Manual.

ADDITIONAL ITEMS NEEDED

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

HOW TO PERFORM THE TEST

1. Remove the test strip from the sealed pouch.
2. 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).
3. Lay the test strip flat on a clean, dry, and non-absorbent surface.
4. Read the result between 3 and 5 minutes.



IMPORTANT:

Do not allow the urine level to exceed the MAX (marker line); otherwise, the test will not perform correctly.

HOW TO READ THE RESULTS

Positive(Pregnant)

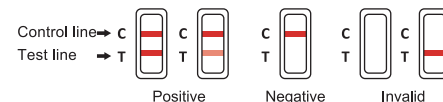
Two distinct color lines appear in the Control and Test Zones. One line should be in the control zone (C) and another line should be in the test zone (T).

Negative(Not pregnant)

Only one-color line appears in the control zone (C). No apparent color line in the test zone (T).

Invalid

The result is invalid if no visible line appears in the control zone (C), even if a line appears in the test zone (T). You should repeat the test with a new test strip.



NOTE:

The color intensity of the test lines may vary since different stages of pregnancy have different concentrations of hCG hormone. If the color of the test lines is faint, it is recommended to repeat the test in 48 hours.

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 the result is negative and you still suspect you may be pregnant, you should wait a few more days and repeat the test. If you continue to have questions or concerns, you should contact your physician.

See also "**Limitations**"

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) confirms that the reagents are working properly, a sufficient specimen volume is used, and the correct procedure was followed.

If the test does not show any control or test line in the testing window, the test should be discarded. Repeat the

test with a new strip and follow the procedure exactly. If the second test does not show lines, please contact us for further assistance.

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. Low concentration of hCG in very early pregnancy can give a negative result. In this case, another test should be repeated at least 48 hours later.
3. Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine specimens should not be used alone to diagnose pregnancy unless these conditions have been ruled out.
4. Certain health conditions, such as an ovarian cyst or ectopic pregnancy, can cause false or irregular results.
5. The test is for early detection of pregnancy only.
6. Elevated levels of hCG have been found in patients with gestational and non-gestational trophoblastic disease. Where appropriate, these conditions should be ruled out before a diagnosis of pregnancy is reached.
7. Abnormal pregnancy cannot be distinguished from normal pregnancy based on hCG measurements alone.
8. Drugs that contain hCG, such as Pregnyl, Profasi, Pergonal, and APL, can give a false positive result.








EXPECTED RESULTS

Negative results are expected in healthy non-pregnant women. Healthy pregnant women have hCG present in their urine specimens. The amount of hCG will vary greatly with gestational age and between individuals. The Premom Pregnancy Test Strip can be used as early as the first day of the missed period.

QUESTIONS AND ANSWERS

1. **Is a significant difference between the control lines of two tests a concern?**
No, variations in the color of the control line will not affect the test result.
2. **Can test results be interpreted after more than five minutes?**
No, test results must be read within 5 minutes. Although 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. Always read the results within the testing period to avoid confusion.
3. **Is the appearance of a pink background color and vertical streaking during the testing period a concern?**
No, variations in urine chemical makeup and testing conditions can cause the vertical streaking and pink-rose background color, but they will not affect the test results. As long as the control line appears within 5 minutes, the test is working correctly.

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
-  Contains sufficient for <n> tests

Questions or comments?
Please call toll-free:
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