



Pregnancy Test

User Manual

Catalog No.: PMS1-M



INTENDED USE

Premom® HCG Urine Test is a rapid pregnancy test, which you can easily carry out yourself. It detects the presence of human chorionic gonadotropin (HCG), which appears in urine very early during pregnancy.

For *in vitro* self-testing use only. For external use only.

HOW DOES IT WORK

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

When the test is inserted to 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 colored line. Absence of this colored 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.

HOW TO DO THE TEST

- To begin testing, open the sealed pouch by tearing along the notch. Remove test device--midstream from the pouch.
- Hold the round end of cover with one hand. Use the other hand to pull out the midstream cap and expose the absorbent.

Place the absorbent tip in urine stream for **10 seconds** to be thoroughly wet.



OR

Collect your urine into a clean cup and dip the absorbent pad completely into the urine for **10 seconds**.



- Re-cap the device and wait for color bands to appear. Positive results may be observed in as soon as 1 minute.

However, the complete reaction time of 3 minutes is required. User should read results between 3 and 5 minutes. Do not read results after 5 minutes.



3-5minutes

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. 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 test still fails, please contact the distributor or the store, where you bought the product, with the lot number.



Positive



Negative



Invalid

NOTE: if the color in the Test Zone is weak, it is recommended that the test be repeated in 48 hours.

STORAGE AND STABILITY

- Store at 4°C to 30°C (39°F to 86°F) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.
- Preferably open the pouch only shortly before the test.

CONTENT OF THE KIT

- One pouch containing a midstream and desiccant. The desiccant is for storage purpose only and is not used in test procedure.
- One instruction manual

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Urine collection cup

WHEN TO DO THE TEST

Any urine specimen is appropriate for pregnancy testing but the first morning urine specimen is optimal because of its highest concentration of HCG.

WHAT TO DO WHEN YOU KNOW THE RESULT

IF THE RESULT IS POSITIVE (TWO LINES)

Consult your physician. They should confirm your pregnancy after evaluating all clinical and laboratory findings. Indeed, in certain conditions, the test may give a false positive result. They will also give you further information and advise 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. no menstrual bleeding), you can repeat the test a few days later. If the test is still negative, consult your physician.

See also "Limitations".

LIMITATIONS

- As it is with any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
- 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.
- 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.
- 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 to diagnose pregnancy unless these conditions have been ruled out.
- A normal pregnancy can not be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
- Sterility treatments, based on hCG, may cause false results. Consult your physician.

EXPECTED RESULTS

Negative results are expected in healthy non-pregnant women and healthy men. Although the hCG levels in normal early pregnant women are variable, Premom® Pregnancy Test is capable of detecting pregnancy as early as 1 day after the first missed menses.

QUESTIONS & ANSWERS

Q: There is much difference between the control lines of two tests. Is this a concern?

A: No. Variations in the color of the control band will not affect the test result.

Q: Can test results be interpreted after more than five minutes?

A: No. Test results must be read in 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.

Q: I have waited longer than 5 minutes, and still there are no lines in the result window. What does this mean?

A: There should always be at least one pink line in the result window at 5 minutes. If not, the test is invalid. The invalid results are normally caused by 3 major reasons: not placing absorbent tip in urine for enough 10 seconds, urine is insufficient or urinated past the arrow line on the pad. You should retest with another test and make sure place the absorbent tip in urine for 10 seconds meantime make sure urine is sufficient and avoid urinating past the arrow line on the pad. If you still see the invalid result, contact the vendor.

PRECAUTIONS

Keep out of the reach of children.
Store between 4°C and 30°C (39°F and 86°F)
Do not re-use.

Do not use test kit beyond expiry date.
Do not use the kit if the pouch is punctured or not well sealed.

MEANING OF SYMBOLS



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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