



Pregnancy Test Strip

Wondfo® Pregnancy Test Strip (Catalog# W1-S25 for 25 Tests/Box)

Wondfo® Pregnancy Test Strip (Catalog# W1-S for 20 Tests/Bag)

Wondfo® Pregnancy Test Strip is a rapid, one step immunoassay for the detection of human chorionic gonadotropin (hCG) in urine.

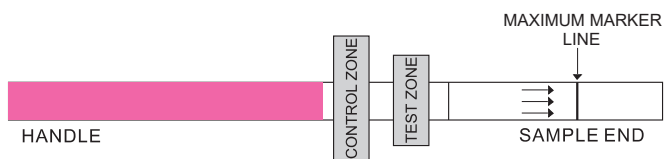
For *in vitro* diagnostic use. It is intended for over-the-counter use.

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

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



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. Package Insert.

WHAT ELSE DO YOU NEED ?

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

PRECAUTIONS

1. The test 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 expiration date.
4. Do not use the test 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-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. Preferably open the pouch only shortly before the test.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR 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.

HOW TO COLLECT URINE?

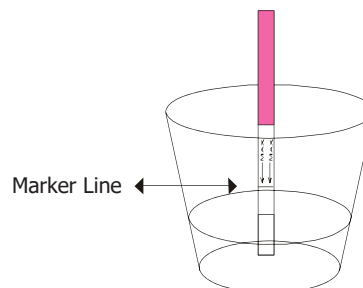
Urine specimens may be collected in any clean, dry, plastic or glass container.

HOW TO DO THE TEST?

1. The test strip and urine must be at room temperature 59°F-86°F (15°C-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 3-5 minutes. **Do not read results after 5 minutes.**



HOW TO READ THE RESULTS

Negative (Not Pregnant):

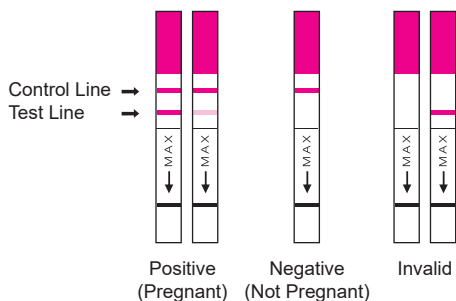
Only one colored band appears in the Control Zone. No apparent band in the Test Zone. This indicates that no pregnancy has been detected.

Positive (Pregnant):

Distinct colored 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 colored band at all or there is a visible colored band only in the Test Zone and not in the Control Zone. 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.



NOTE: If the color in the Test Zone is weak, it is recommended that the test should be repeated with a new test strip in 48 hours.

WHAT TO DO WHEN YOU KNOW THE RESULT

IF THE RESULT IS POSITIVE (TWO LINES)

Consult your physician who should confirm your pregnancy after evaluating all clinical and laboratory findings. Indeed, in certain conditions, the test may give a false positive result. Your physician will also give you further information and advice on your pregnancy. Please also refer to "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 with a new test strip a few days later. If the test result is still negative, consult your physician. Please also refer to "Limitations".

LIMITATIONS

- As any diagnostic procedure, the confirmed pregnancy diagnosis should only be made by your physician after evaluating all clinical and laboratory findings.
- If the urine specimen 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 the 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.
- The 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, Wondfo® Pregnancy Test Strip is capable of detecting pregnancy as early as 1 day after the first missed menses.

QUESTIONS & ANSWERS

1. If there is a difference between the color or intensity of control lines between two tests. Is this a concern?

No. Variations of 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 3-5 minutes. Although a positive result should not change for several days, a negative result may change to a false positive within minutes after the test period ends, which would not be an accurate reading. It is always best to read the results in 3-5 minutes testing period and then discard the test after 5 minutes 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 testing chamber (room). Such variations of 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 five minutes, the test is working properly.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-844-337-2743.

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



Instruction for use



For *in vitro* diagnostic use

Manufactured by Guangzhou Wondfo Biotech Co., LTD.
Guangzhou, Guangdong, P.R. China 510663
Made in China

Rev. A1
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