

The Wondfo One Step 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 urine specimen is applied to a midstream, 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.

CONTENT OF THE TEST KIT

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

WHAT ELSE DO YOU NEED?

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

PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test midstream cannot be used more than once.
3. Do not use test kit beyond expiry date.
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 4°C to 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.

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.

HOW TO DO THE TEST?

1. To begin testing, open the sealed pouch by tearing along the notch. Remove test device—midstream from the pouch.
2. Hold the round end of cover with one hand. Use the other hand to pull out the midstream cap and expose the absorbent.
3. Point the absorbent tip downward; place the absorbent tip in urine stream for at least 10 seconds to be thoroughly wet. Do not urinate passed the arrow mark. Otherwise, you can collect your urine into a clean cup and dip half of the absorbent pad into the urine for at least 3 seconds.
4. Re-cap the device and wait for color bands to appear. Positive results may be observed in as soon as 1 minute. However, to confirm negative results, the complete reaction time of 3 minutes is required. Do not read results after 5 minutes.



HOW TO READ THE RESULTS?

Negative (not pregnant):

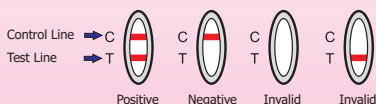
Only one color band appears, in the control zone. No apparent band on the test zone. This indicates that no pregnancy has been detected.

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 but 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.



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

WHAT TO DO WHEN YOU KNOW THE RESULT

IF THE RESULT IS POSITIVE (TWO LINES)

Consult your physician. He should confirm your pregnancy after evaluating all clinical and laboratory findings. Indeed, in certain conditions, the test may give a false positive result. He 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

1. 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.
2. 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.
3. 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.
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 to diagnose pregnancy unless these conditions have been ruled out.
5. 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.
6. Sterility treatments, based on HCG, may cause false results. Consult your physician.
7. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of HCG.
8. The device is only suitable for human urine test.
9. Unclean specimen or interfering substances in the urine may cause false result.
10. Unclean test device or wrong operation may cause false result.

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, One Step HCG Urine Test is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Sensitivity

One Step HCG Urine Test will detect urine HCG concentration of 25mIU/mL or greater.

Specificity

The specificity of the One Step HCG Urine Test was determined from cross-reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). Negative results were obtained from all tests conducted with 300 mIU/ml hLH, 300 mIU/ml hFSH and 1000 μ IU/ml hTSH.












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 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.
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 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 five minutes, the test is working properly.

BIBLIOGRAPHY

1. Canfield RE, Morgan FJ, Kammerman S, Bell JJ, Agosto GM. Studies of human chorionic gonadotropin. Recent Prog Horm Res. 1971; 27:121-164.
2. Ross GT. Clinical relevance of research on the structure of human chorionic gonadotropin. American Journal of Obstetrics and Gynecology 1977; 129:795.

MEANING OF SYMBOLS ON PACKAGE

 IVD in vitro Diagnostic Use Only	 See Instruction for Use	 Expiry Date
 Manufacturer	 Catalog #	 Keep Dry
 LOT Batch Number	 Authorised representative in the European Community	 Keep away from Sunlight
 Store between 4-30°C	 Do not reuse the sticks	

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