

About the Test

HORMONElife™ Pregnancy Test Strip is a rapid pregnancy test which you can easily carry out by yourself. It detects the presence of human chorionic gonadotropin (hCG), which appears in urine very early during pregnancy.

How the Test Works

Human chorionic gonadotropin (hCG) is a hormone produced by the developing placenta shortly after the conception and it is secreted into the urine. The HORMONElife™ Pregnancy Test Strip 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 (T) region of the membrane, it will form a colored band. Absence of this colored band suggests a negative result.

To serve as a procedure control, a colored band will appear in the Control Zone (C), if the test has been performed properly.

All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

For *in vitro* diagnostic use.

This product is intended for over-the-counter (OTC) use.

How to Test

1. The test strip and urine have to be at room temperature 59°F–86°F (15°C–30°C) for testing.
2. Remove the test strip from the sealed pouch.

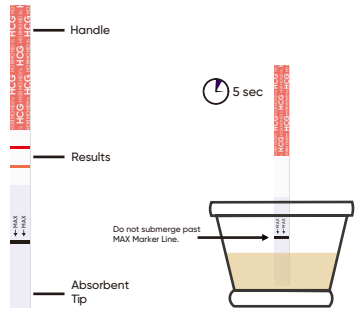
1 Test first thing in the morning:

Any urine specimen is appropriate for pregnancy test, but the **first morning urine** specimen is optimal because of its highest concentration of hCG. hCG may be detectable with this test by the day after the missed period. If you need to test later in the day, avoid lots of fluids as water can dilute urine and impact your result.

2 How to test:

Pee in a dry and clean cup, and dip the absorbent end of the strip into the urine for 5 seconds until the dye rises. Take the strip out and lay the strip flat on a clean, dry and non-absorbent surface.

NOTE: Do not submerge past the MAX Marker Line. This will cause the test not to perform correctly.



3 Read results in 3-5 minutes:

Lay the strip flat and face up. Wait 3-5 minutes before reading. Read your result in 3-5 minutes. **Do not read results after 5 minutes.**



Negative (Not Pregnant):

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

Positive (Pregnant):

Two distinct colored bands appear in the Control and Test Zones. This indicates you are pregnant. The color intensity of the test lines may vary since there are different concentrations of hCG in different stages of pregnancy. If you see a faint positive, we recommend retesting 48 hours later, with your first morning urine specimen to confirm.

Invalid Test:

There is a visible colored band only in the Test Zone (T) or no visible colored bands in both of the zones. Repeat with a new test. If test still fails, please contact the distributor or the store where you bought the product with the lot number.

Interpreting Results

If the result is positive (two lines):

Consult your doctor, who should confirm your pregnancy after evaluating all clinical and laboratory findings. In certain conditions, the test may give a false positive result. Your doctor will also give you further information and advice on your pregnancy.

Also see "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 2 days later. If the test is still negative, consult your doctor.

Also see "Limitations"

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, HORMONElife™ Pregnancy Test Strip is capable of detecting pregnancy as early as 1 day after the first missed menses.

Limitations

1. As it is with any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by your doctor after evaluating all clinical and laboratory findings.
2. 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.
3. 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.
4. 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.
5. Sterility treatments, based on hCG, may cause false results. Consult your doctor.

Important Information

Test Kit Contents

- 1. HORMONElife™ Pregnancy Test strip (s), each in one pouch with desiccant. The desiccant is for storage purposes only and is not used in the test procedure.
- 2. One (1) Package Insert

Additional Items Needed

- 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 kit 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 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.

Frequently Asked Questions

1. 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 where you test. Variations in physical conditions can cause the vertical streaking or the pink background color but will not affect the test results. If the control band appears within five minutes, the test is working properly.

2. Can test results be interpreted after more than five minutes?

No. Test results must be read in 3-5 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.

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

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

4. Do I have to use an early morning urine sample?

We recommend you test with your first urine of the day. Any urine specimen is appropriate for pregnancy test, but the first morning urine specimen is optimal because of its highest concentration of hCG.

5. Can any medication or medical condition affect the results?

Any medical procedure which involves hCG, such as fertility treatments, may cause false results. Please discuss them with your doctor if you do get unexpected results.

6. What if I am unsure with my result (faint/light line)?

It is recommended that weak positive test results should be confirmed by retesting an early morning (first) urine specimen 48 hours later. A significant number of first trimester pregnancies terminate for natural reasons.

If you have any question regarding to the use of this product, please call our Toll-Free Number 1-888-444-3657 (9:00 a.m. to 5:30 p.m. CDT M-F), or reach out to us via our website:

 www.hormonelifelife.com

Meaning of Symbols on Package

	Keep away from sunlight		Temperature limit 86°F/30°C 39°F/4°C		Keep dry
	Do not re-use		In vitro diagnostic medical device		Consult instructions for use

Distributed by Wondfo USA Co., Ltd.

890 Remington Blvd
Bolingbrook, IL 60440
+1 (630) 468-2199
Made in China

Rev. A1.1
Rel.: 2025/11/28



Pregnancy Test Strip

Cat. No.: See Box Label



物料编码: 13029365

项目名称: 25mIU hCG条OTC说明书英文版(279x108mm)美国电商HLV02

尺寸(长*宽*高): 279x108mm

颜色:  C83M100K44  M70Y50 材质: 80g铜板纸

工艺:

折页方式: 长边风琴3折4页
红色虚线为折页, 非印刷内容

修改内容: ☒ 文字 ☐ 颜色 ☐ 尺寸 ☐ 工艺 ☐ 材质 ☐ 其他 ☐ 无

改稿前编码: 13026930

申请人: 刘思莹

设计师: 申芳

设计时间: 2025.11.28

稿件确认签名:

廖金英

申芳 邓素秋

刘思莹