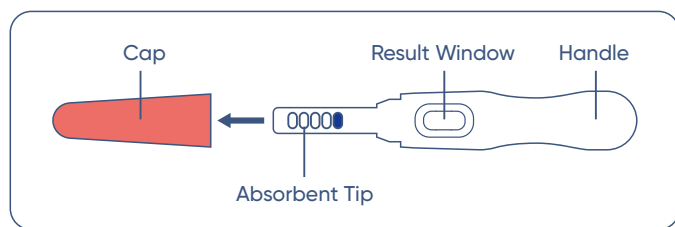




HORMONELife™

Pregnancy Home Test Midstream

Catalogue No. See Box Label



HORMONELife™ Pregnancy Home Test Midstream 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.

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 it is secreted into the urine. The HORMONELife™ Pregnancy Home Test Midstream contains antibodies which specifically react with this hormone.

When urine specimen is dropped onto a midstream, capillary action carries the specimen along the membrane. When hCG in the specimen reaches the Test Zone (T) 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.

CONTENT OF THE TEST KIT

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

WHAT ELSE DO YOU NEED

1. A clean, dry, plastic or glass container to collect the urine (Optional).
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.

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.

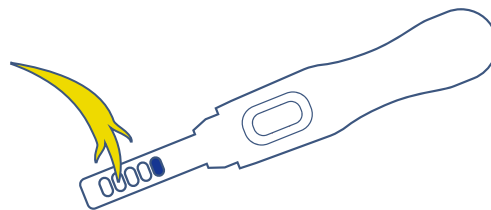
HOW TO DO THE TEST?

1. The midstream test and urine should be at room temperature 59°F – 86°F (15°C – 30°C) for testing.
2. Open the sealed pouch by tearing along the notch. Remove the midstream from the pouch.
3. Hold the handle with one hand. Use the other hand to pull out the midstream cap and expose the absorbent tip.
4. You can test directly in your urine stream, or dip into your collected urine specimen.

a) Urine Stream

Point the absorbent tip downward; place the absorbent tip in your urine stream for at least 5 seconds to make it wet thoroughly.

Do not urinate past the blue mark.

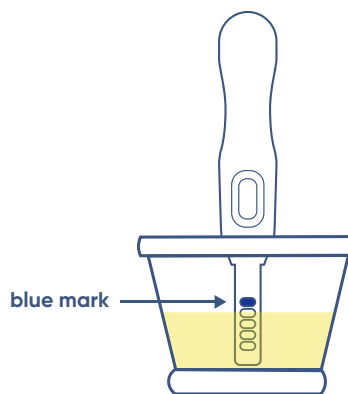


OR

b) Collected Specimen

You can collect your urine into a clean cup and dip the absorbent tip into the urine for at least 5 seconds.

Do not allow the urine level to reach the blue mark.



5. Re-cap the device and wait for colored bands to appear. 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 (C). No apparent band in the Test Zone (T). This indicates that no pregnancy has been detected.

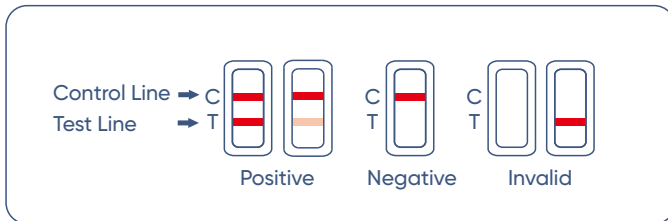
Positive (Pregnant):

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 (T) and not in the Control Zone (C). Repeat with a new test kit. If test still fails, please contact the distributor or the store where you purchased the product with the lot number.



NOTE: If the color in the Test Zone (T) is weak, it is recommended that repeat the test 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.

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 result is still negative, consult your physician.

Also see "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 the urine sample is too dilute (ie, low specific gravity), it may not contain the 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 cannot 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.

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 Home Test Midstream is capable of detecting pregnancy as early as 1 day after the first missed menses.

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 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. It is always best to read the results in 3-5 minutes 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.

ASSISTANCE

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 THE PACKAGE



Keep away from sunlight



Store between 39°F-86°F (4°C-30°C)



Keep dry



Do not re-use



Consult instructions for use



In vitro diagnostic medical device

Distributed by Wondfo USA Co., Ltd.
890 Remington Blvd
Bolingbrook, IL 60440
+1 (630) 468-2199
Made in China

Rev. A1
Rel.: 2025/09/19



物料编码: 13028909

项目名称: 25mIU-HCG M笔OTC说明书(210x285mm)HORMONElife

尺寸(长*宽*高): 210x285mm

颜色:  C83M100K44  M70Y50  C76M56Y20K29

材质: 80g双铜

工艺:

折页方式: 长边风琴4折5页+左右对折 修改内容: ☐文字 ☐颜色 ☐尺寸 ☐工艺 ☐材质 ☐其他 ☐无

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