



Pregnancy Test

PHARMACY ACTION Pregnancy Test is a quick pregnancy test, which can easily be carried out by yourself from the first day of delay in periods. It detects the presence of human chorionic gonadotropin (HCG), which appears in urine very early during pregnancy.

\*according to clinical study >99% of the tested samples showed correct results when tested after the first day of missed period.

Sensitivity 20 IU/L

Device for self-testing

How does it work?

During pregnancy the woman develops the hormone human chorionic gonadotropin (HCG) which can be detected in the urine. The pregnancy test contains antibodies which specifically react with this hormone.

When a urine sample is dropped onto a midstream test, capillary action carries the sample along the membrane. When HCG in the sample reaches the test zone window of the membrane (T), it will form a coloured line. Absence of this coloured line suggests a negative result. To serve as a procedure control, a coloured line will appear at the control zone window (C), if the test has been performed properly.

Contents of the test kit

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

What else do you need?

- 1. If you do not wish to urinate directly on the strip of the test, you can use a plastic or glass container to collect the urine. Make sure the container is clean and dry.
- 2. Timer (watch or clock).

Precautions

- 1. This kit is for external use only. Do not swallow.
- 2. Discard after use. The test strip cannot be used more than once.
- 3. Do not use the test kit after its expiry date.
- 4. Do not use the kit if the pouch is punctured or not sealed properly.
- 5. Keep out of reach of children.

Storage and Stability

- 1. Store at 4°C to 30°C and in the sealed pouch up to the expiration date.
- 2. Keep away from direct sunlight, moisture and heat.
- 3. Do not freeze.
- 4. Only open the pouch shortly before carrying out the test.

Instructions for use

When to carry out the test?

Any urine sample is appropriate for pregnancy testing, but a sample of the first morning urine is optimal because it has the highest concentration of HCG.

How to carry out the test?

- 1. To begin testing, open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
- 2. Hold the round end of the test with one hand. Use the other hand to remove the cap and expose the absorbent tip.
- 3. Point the absorbent tip downward; place the absorbent tip in the urine stream for at least 10 seconds to be thoroughly wet. Do not urinate past the arrow mark.
- 4. Alternatively you can collect your urine into a clean cup and dip half of the absorbent pad into the urine for at least 3 seconds.
- 5. Put the cap back on the device and wait for the colour lines 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 colour line appears in the control zone (C). No apparent line in the test zone (T). This indicates that pregnancy has not been detected.

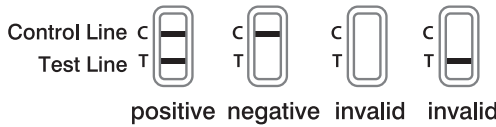
Positive (pregnant):

Distinct colour lines appear in the control and test zones. This indicates that you are pregnant. The colour intensity of the test lines may vary from test to test since different stages of pregnancy have different concentrations of HCG hormone.

Invalid:

No visible line at all, or there is a visible line only in the test region and not in the control region. Repeat the test with a new test kit.

If the test still fails, please contact a doctor or a pharmacist where you bought the product with corresponding lot number.



NOTE: If the colour in the test zone is very weak, it is recommended that the test is repeated after 48 hours.

What to do when you know the result?

If result is positive (two lines) consult your physician. He should confirm your pregnancy after evaluating all clinical and laboratory findings.

Under certain conditions, the test may give a false positive result. He will also give you further information and advice 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 is the case with any self-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 (i.e. low specific gravity) it may not contain a representative level of HCG. If a pregnancy is still suspected, another urine sample should be collected 48 hours later and tested.
- 3. Low concentration of HCG in early pregnancy can give a negative result. In this case, another urine sample 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 a urine sample should not be used to diagnose pregnancy unless these other 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 doctor.

Expected results

Negative results are expected in healthy non-pregnant woman. Although the HCG levels in normal early pregnant women are variable, PHARMACY ACTION pregnancy test is capable of detecting pregnancy as early as 1 day after the first missed menstrual bleeding.

Questions & answers

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

No. Variations in the colour of the control line will not affect the test result.

2. Can test results be interpreted after more than 5 minutes?

No. Test results must be read within 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 end of the testing period, which would not give an accurate reading. It is always best to read the results within the 5 minutes testing period and then discard the test to avoid confusion.

3. A pink background colour 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 the room where the test is performed. Such variations in physical conditions can cause the vertical streaking and/or the pink background colour but will not affect the test results. As long as the control line appears within 5 minutes, the test is working properly.

**Manufacturer:**  
HELM Medical GmbH,  
Nordkanalstraße 28,  
20097 Hamburg, Germany

**Distributor:**  
Generic Health Pty Ltd  
Level 1, 1102 Toorak Road  
Camberwell VIC 3124

Explanation of Symbols on Package:

- Keep away from sunlight
- Store between 4 °C and 30 °C
- Keep dry
- Do not re-use
- Attention to the instructions for use
- In vitro diagnostic medical devices
- Expiry Date
- LOT Number
- sufficient for 1 test
- sufficient for 2 tests

This leaflet was issued in October 2014 L-PTM00017- 01 0123

Dimensions: 180 x 224 mm

Colours: BLACK