BIOTEST

Your reliable home test kits series

Pregnancy Test Kit (cassette)

CE 0459

Product Code 9 555 223 208 029
For in vitro diagnostic and self testing use.
Store at 2-30ºC

INTENDED USE

BIOTEST Home Pregnancy Test Kit (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

HOW TO USE THE TEST

Refer to the illustration below

Step 1:

- Read instructions carefully before use.
- Collect fresh urine sample (preferably first morning specimen) in a clean and dry disposable container. The container has to be devoid of any detergent traces.

Step 2:

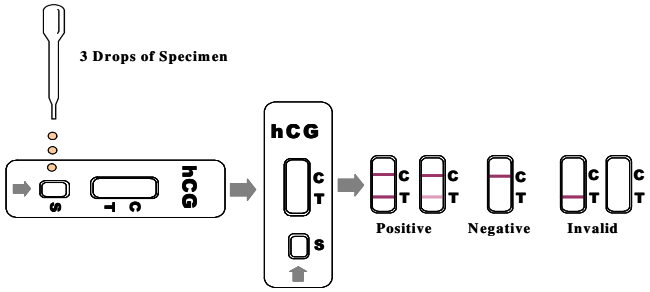
- Check that the test is completely sealed then open the pouch and place the test device on a flat surface

Step 3:

- With the dropper provided, transfer 3 or 4 drops of the sample to the sample well in the test device.

Step 4:

- Read results within 5 minutes. Look for colored bands (lines) to appear in the rectangular area.
- Test results should not be read after 10 minutes.



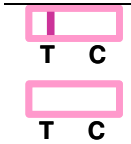
HOW TO READ THE RESULTS



PREGNANT
Positive results: 2 bands.
The presence of two red lines in the result window means you are probably pregnant. One line may be lighter than the other; they do not have to match. Check with your doctor to confirm pregnancy.



NOT PREGNANT
Negative results = one band in the (C) area.
The presence of one red line in the control **area** (C) means you are probably not pregnant.



INVALID RESULT
Invalid results = no bands or 1 band in the (T) area.
The result is invalid if no red line appears in the control area (C), even if a line appears in the test area (T). You should repeat the test with a new test.

PRECAUTIONS & WARNINGS

1. Do not use the test after the expiration date.
2. If the package is not completely sealed do not use the test.
3. The test should be performed in a well-lit area.
4. Use the test device immediately after opening it.
5. Use the dropper inside the package. Do not use an external dropper.
6. Do not touch the test window. This could affect results and may also impose personal hazards.
7. Use a disposable sample container to be discarded after performing the test.
8. The pouch contains a Silica Gel pack to absorb humidity. Do not open the pack. Throw it away with the remaining of the test.
9. At the end of the test, wrap every thing you have used in a plastic bag and throw away in the bin. Do not forget to wash your hands properly.
10. The remaining sample should be discarded and flushed in the toilet.

CONTENTS

- Test Device
- Dropper
- Desiccant
- Package insert

WHAT THE RESULTS MEAN?

A positive result indicates that your urine contains hCG (the pregnancy hormone) at a concentration more than or equal to 25mIU/ml which is our device sensitivity and you can assume you are pregnant. You should consult your doctor who is best able to further advise you on proper prenatal care. If you are taking medication, inform your doctor immediately and make sure it is safe for your baby.

A negative result means that no hCG has been detected and you can assume you are not pregnant. If a week passes and your menstrual period is still delayed, you should do another test after two days. If the result is still negative in the later test, there is little chance that you are pregnant. However, because there could be health-related reasons why you are not menstruating, you should see your doctor without delay.

If your menstrual cycle is irregular, it can be difficult to know the day you have missed your period. If your test indicated you are not pregnant and your menstrual cycle does not begin within a few days, you may have miscalculated your cycle and should use a second test after two days.

LIMITATION OF THE TEST

The test is not reusable and works only if the instructions are followed precisely. Although the test is highly accurate in detecting pregnancy, a low incidence of false results can occur. Check with your doctor if you get unexpected or inconsistent test results. Certain health conditions can also cause a false or irregular test result.

QUESTIONS & ANSWERS

Q. How does the test work?
A. When a woman is pregnant; her body produces a special pregnancy hormone known as hCG (human Chorionic Gonadotropin). This hormone appears in the urine as early as the first day of a missed menstrual cycle. A positive result indicates that your urine contains hCG and you can assume you are pregnant. A negative result means that no hCG has been detected and you can assume you are not pregnant.

Q. What if the two pink lines appear, but one is much lighter than the other, am I pregnant?
A. Yes. You should assume you are pregnant.

Q. Would I still get accurate results even if I miscounted the number of urine drops?
A. Usually one drop more or less does not affect the test result. As long as a pink line appears in the "C" area, the test had performed correctly. If the pink line in the "C" area does not appear, try to add one or two additional drops of urine. If after five minutes, a pink line does not show in the "C" area, the test is invalid. A new test should be used.

Q. What if I am uncertain about the pink line in the "T" area?
A. It is recommended that you retest three days later using other tests.

Q. Can the result change after a certain length of times?
A. A positive test result might not change after the test is completed and several hours thereafter. However, a negative test result should not be read after 10 minutes.

IFU-BT-HCG-C.v2.2011

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www.bio-test.info