

One + Step® Pregnancy Midstream Test (Urine)

For self-testing and In Vitro diagnostic use only



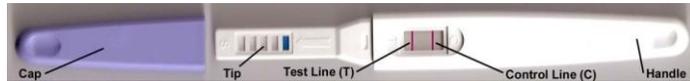
PRINCIPLE

The One Step Pregnancy Midstream Test is a rapid, one-step lateral flow immunoassay in midstream format for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by adding urine to the hydrophilic stick and obtaining the result from the coloured lines.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 2-30°C or 35.6-86°F. Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For in vitro diagnostic use. Not to be taken internally.
- Do not open the test midstream foil pouch until you are ready to start the test.
- The used test midstream should be discarded as per local regulations.



HOW TO USE THE TEST

1. Remove the midstream test from the foil pouch and remove the purple cap.
2. Hold the midstream test by the handle with the exposed Tip pointing downward, directly into your urine stream for at least 15 seconds until it is thoroughly wet.
3. Alternatively, you can urinate into a clean and dry container, then dip only the Tip of the midstream test into the urine for at least 15 seconds.
4. After removing the midstream test from your urine, immediately replace the purple Cap over the Tip, lay the midstream test on a flat surface with the Test and Control window facing upwards, and then begin timing.
5. Wait for the coloured bands to appear. Positive results may be visible within 1 minute but to confirm a negative result wait up to 10 minutes and until the background is clear. Results obtained after 10 minutes may be considered invalid.

HOW TO READ THE RESULTS



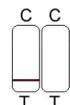
PREGNANT

The presence of two red lines in the test (T) and control (C) window, one red line next to the (T) and one red line next to the (C) window, means you are probably pregnant. One line may be lighter than the other, they do not have to match.



NOT PREGNANT

The presence of just one red line next to the control (C) window means you are probably not pregnant.



INVALID RESULT

The result is invalid if no red line appears in the control (C) window. This indicates that you either did not get enough urine on the test or you have flooded the test. Flooding the test can occur if you do not hold the test with the Tip pointing downward whilst testing, if the test was immersed for longer than 10 seconds, if urine goes above the arrow or if you hold the test upside down. You should repeat the test with a new midstream test making sure to follow the instructions fully.

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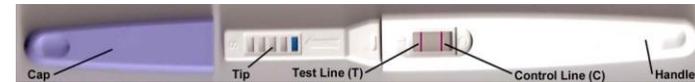
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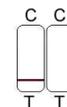
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LIMITATIONS

There is the possibility that this test may produce false results. Consult your physician before making any medical decisions.

1. Drugs which contain hCG (such as Pregnyl, Profasi, Pergonal, APL) can give a false positive result. Alcohol, oral contraceptives, painkillers, antibiotics or hormone therapies that do not contain hCG should not affect the test result.
2. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50mIU/ml) are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons¹, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumours, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG^{2,3}. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test may produce false negative results. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

ADDITIONAL INFORMATION

1. *How does the test work?*

The One Step Pregnancy Midstream Test detects a hormone in your urine that your body produces during pregnancy (hCG-human chorionic gonadotropin). The amount of pregnancy hormone increases as pregnancy progresses.

2. *How soon after I suspect that I am pregnant can I take the test?*

Although these tests can show positive before your period is due, we recommend you wait until the first day of missed period.

3. *Do I have to test with first morning urine?*

Although you can test at any time of the day, your first morning urine is usually the most concentrated of the day and would have the most hCG in it.

4. *How accurate is the test?*

A clinical evaluation was conducted comparing the results obtained using this Midstream Test to another commercially available urine membrane hCG test. The consumer clinical trial included 608 urine specimens: both assays identified 231 positive and 377 negative results. The results demonstrated >99% overall accuracy of the One Step Pregnancy Midstream Test when compared to the other urine membrane hCG test.

5. *How sensitive is the test?*

The One Step Pregnancy Midstream Test detects hCG in urine at a concentration of 10 mIU/mL or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 μ IU/mL) to negative (0 mIU/mL hCG) and positive (10 mIU/mL hCG) specimens showed no cross-reactivity.

6. *What should I do if the result shows that I am pregnant?*

It means that your urine contains hCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.

7. *How do I know that the test was run properly?*

The appearance of a coloured line in the control line region (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.

8. *What should I do if the result shows that I am not pregnant?*

It means that less than 10 mIU/mL hCG has been detected in your urine and probably you are not pregnant. If you do not start your period within a week of its due date, repeat the test with a new test midstream. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

BIBLIOGRAPHY

1. Steier JA, P Bergsjo, OL Myking Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy, *Obstet. Gynecol.* 1984; 64(3): 391-394
2. Dawood MY, BB Saxena, R Landesman Human chorionic gonadotropin and its subunits inhydatidiform mole and choriocarcinoma, *Obstet. Gynecol.* 1977; 50(2): 172-181
3. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopicproduction of human chorionic gonadotropin by neoplasms", *Ann. Intern Med.* 1973; 78(1): 39-45

Manufactured by: Hangzhou AllTest Biotech Co.,Ltd. #550, Yin Hai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R.China.

EC REP: MedNet GmbH, Borkstrasse 10, 48163 Muenster, Germany.

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