

Pregnancy Test

Early detection • hCG pregnancy enhanced sensitivity rapid test midstream urine with indicator

ENGLISH

[INTENDED USE]

The Pregnancy Test (hCG pregnancy enhanced sensitivity rapid test midstream) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

[PRINCIPLE]

The Pregnancy Test (hCG pregnancy enhanced sensitivity rapid test midstream) is a rapid, one-step lateral flow immunoassay in midstream format for the qualitative detection of hCG in urine to aid in the early detection of pregnancy. The test utilises 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 foil pouch until you are ready to start the test.
- The used test should be discarded according to local regulations.

[MATERIALS PROVIDED]

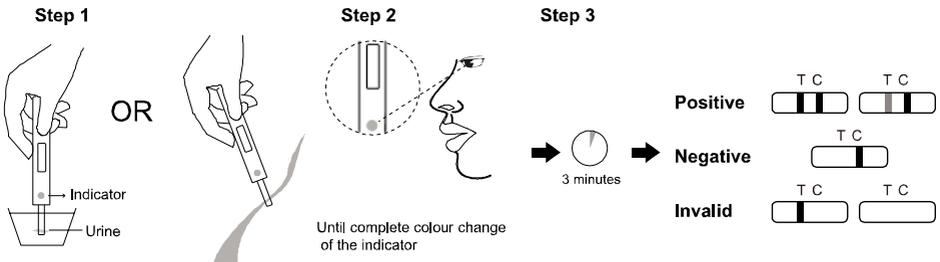
- Midstream test
- Package insert

[MATERIALS REQUIRED BUT NOT PROVIDED]

- Timer
- Specimen collection container

[INSTRUCTIONS]

1. Remove the cap and place the absorbent tip in your urine stream or in a collected urine sample for 15 seconds.
2. Remove the tip from the urine, replace the cap and place the test stick on a flat surface.
3. After 3 minutes, your result can be read. Do not interpret the results after 10 minutes.



[READING THE RESULTS]

POSITIVE

Two distinct coloured lines appear. One line should be in the control line region (C) and another line should be in the test line region (T). One line may be lighter than the other; they do not have to match. This indicates pregnancy.

NEGATIVE

One coloured line appears in the control line region (C). No line appears in the test line region (T).

This indicates no pregnancy.

INVALID

The result is invalid if no coloured line appears in the control line region (C), even if a line appears in the test line region (T).

You should repeat the test with another midstream test.

[LIMITATIONS]

There is the possibility that this test may produce false results. Consult a 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 reasons,¹ 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.

[EXTRA INFORMATION]**How does the test work?**

The Pregnancy Test (hCG pregnancy enhanced sensitivity rapid test midstream) 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.

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

The test is designed to detect hCG as early as 6 days before your missed period (5 days before day of the expected period). You can perform the test anytime of the day; however, if you are pregnant, first morning urine contains the most pregnancy hormone.

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.

How accurate is the test?

A clinical evaluation was conducted comparing the results obtained using the Pregnancy Test (hCG pregnancy enhanced sensitivity rapid test midstream) to another commercially available urine hCG test. The consumer clinical trial included 358 urine specimens: both assays identified 150 positive and 208 negative results. The results demonstrated >99% overall accuracy of the Pregnancy Test (hCG pregnancy enhanced sensitivity rapid test midstream) when compared to the other urine hCG test.

How sensitive is the test?

The Pregnancy Test (hCG pregnancy enhanced sensitivity rapid test midstream) detects hCG in urine at a concentration of 10 mIU/mL or greater. The test has been standardised 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.

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.

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.

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

It means that no 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 in hydatidiform mole and choriocarcinoma, *Obstet. Gynecol.* 1977; 50(2): 172-181
3. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross Ectopic production of human chorionic gonadotropin by neoplasms", *Ann. Intern Med.* 1973; 78(1): 39-45

Index of Symbols

	Manufacturer		Tests per kit		Authorised Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		