



HCG Pregnancy Rapid Test Cassette (Urine) Package Insert For Self-testing

REF FHC-U102H English

【PRINCIPLE】

HCG Pregnancy Rapid Test Cassette is a rapid, one-step lateral flow immunoassay in device 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 monodonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by adding urine to the specimen well, and obtaining the result from the colored lines.

【PRECAUTIONS】

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

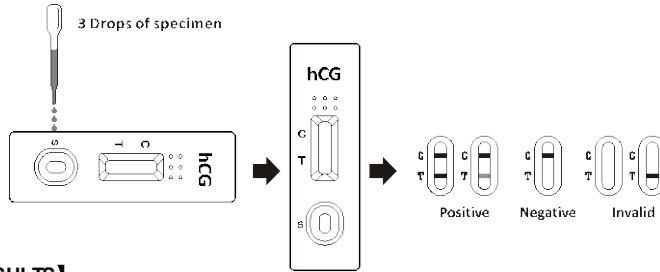
- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 2-30°C or 35.6-86°F. Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For in vitro diagnostic use. Not to be taken internally.
- Do not open the test cassette foil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

【MATERIALS PROVIDED】

- Test cassette
- Dropper
- Package insert

【INSTRUCTIONS】

- Urinate into a clean, dry cup or container.
- Remove the test cassette from the foil pouch and familiarize yourself with the product.
- Hold the dropper vertically and transfer 3 full drops of urine (approximately 120ul) to the specimen well of the test cassette, and then begin timing. Avoid trapping air bubbles in the specimen well. See the illustration below.
- As the test cassette begins to work, you may notice a light colored flow moving across the test line region (T) and control line region (C) on the test cassette. Read the result at 3 minutes. If no colored line appears, wait 1 minute longer. Some positive results may be observed in 1 minute or less depending on the concentration of hCG. Do not read the result after 10 minutes.



【READING THE RESULTS】

POSITIVE

Two distinct colored 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 means that you are probably pregnant.

NEGATIVE

One colored line appears in the control line region (C). No line appears in the test line region (T). This means that you are probably not pregnant.

INVALID

The result is invalid if no colored 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 a new test cassette.

【LIMITATIONS】

There is the possibility that this test cassette 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 tumors, 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 INFORMATIONS】

1. How does the test cassette work?

HCG Pregnancy Rapid Test Cassette 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?

You can test your urine as early as the first day you miss your period. You can perform the test anytime of the day; however, if you are pregnant, first morning urine contains the most pregnancy hormone.

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 the HCG Pregnancy Rapid Test Cassette 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 HCG Pregnancy Rapid Test Cassette when compared to the other urine membrane hCG test.

5. How sensitive is the test?

HCG Pregnancy Rapid Test Cassette 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 µIU/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 colored 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 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 device. 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 Bergsjö, 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

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged				



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