hCG Pregnancy Rapid Test Midstream (Urine)
Package Insert
For Self-testing

REF FHC-103H	English

【INTENDED USE】

The hCG Pregnancy Rapid Test Midstream is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

【PRINCIPLE】

HCG Pregnancy Rapid Test Midstream 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 hydrophil stick and obtaining the result from the colored lines.

【REAGENTS】

The test contains anti-hCG particles and anti-hCG coated on the membrane.

【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 according to local regulations.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30 °C). Do not open the pouch until ready for use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

The urine specimen should be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

If the urine specimen cannot be detected immediately, it should be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

【MATERIALS PROVIDED】

- Test Midstream
- Package Insert

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer
- Specimen Collection Container

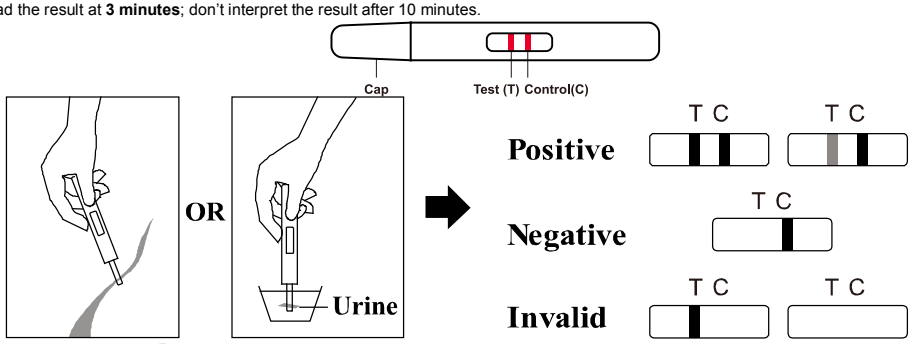
【INSTRUCTIONS】

Allow the test, urine specimen to reach room temperature (15-30°C) prior to testing.

1. Remove the midstream from the foil pouch and test it immediately in one hour.
2. Take down the cap of the midstream, hold the midstream so as to place the absorbent tip in the urine stream or place the absorbent tip (≥2/3) in urine in a clean cup for at least **15 seconds**.

NOTE: Do not urinate on the Result Window.

3. Cover the cap on the testing midstream, then lay down the product on a clean and stable desk, start the timer immediately.
4. Read the result at **3 minutes**; don't interpret the result after 10 minutes.



【READING THE RESULTS】

POSITIVE: Two 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 midstream.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It

confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

【LIMITATIONS】

There is the possibility that this test midstream 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 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 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 midstream work?

HCG Pregnancy 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.

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 Midstream to another commercially available urine 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 Midstream when compared to the other urine hCG test.

5. How sensitive is the test?

HCG Pregnancy Rapid Test Midstream detects hCG in urine at a concentration of 25 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 (25 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 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

	Consult Instructions For Use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 0123

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Number: 145100705
Effective date: 2022-08-08