hCG One Step Pregnancy Test Midstream

Package Insert

Catalogue number:	hCG-103a	Specimen:	Urine
Version:	B	Effective Date:	2022-09-26

For self-testing

【PRINCIPLE】

The hCG One Step Pregnancy Test Midstream is a rapid,one-step lateral flow immunoassay 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 urinating on the Absorbent tip or immersing the Absorbent tip in urine 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 36-86°F. Valid for 24 months. 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.
- DO NOT RE-USE test midstream.

【KIT CONTENTS】

● Test Midstream(s)	● Package insert	● Desiccant(s)

【KIT CONTENTS】（optional）

- Specimen collection container(s) (for specimens collection use)

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer (for timing use)

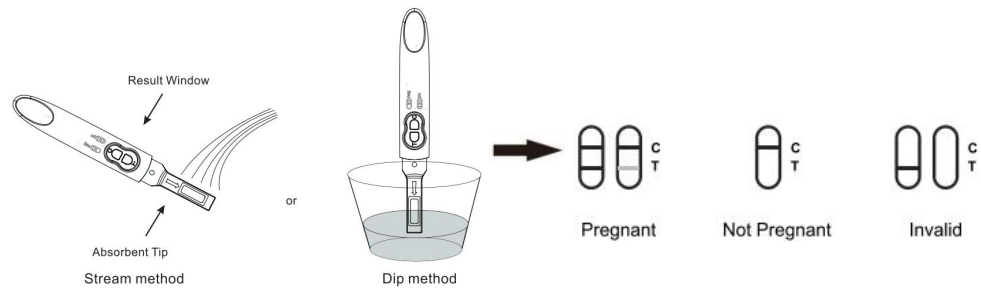
【SPECIMEN COLLECTION AND STORAGE】

- The urine specimen must be collected in a clean and dry container. Urine collected at morning of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.
- Collected urine specimens must be put in clear and dry containers. Ensure that a sufficient quantity of the specimen is collected to allow submerging the dipping area of the device.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods.

【INSTRUCTIONS】

Remove the test from its sealed pouch and use it as soon as possible. To obtain a best result, the assay should be performed within one hour.

1. Remove the midstream test from the foil pouch and familiarize yourself with the product.
2. Hold the midstream test by the Thumb Grip with the **Absorbent tip pointing downward directly into your urine stream for 3-4 seconds**. See illustration below.



3. **NOTE: Do not urinate on the Result window.** If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent tip of the midstream test into the urine for at least 10-15 seconds. Do not pass the arrow on the midstream when dipping the midstream into the urine.
4. After removing the midstream test from your urine, immediately lay the midstream test on a flat surface with the Result window facing upwards, and then begin timing.
5. As the test begins to work, you may notice a light colored flow moving across the Result window. **Read the result at 3 minutes.** If no colored line appears, wait one 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】

PREGNANT

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.

NOT PREGNANT

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】

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The hCG One Step Pregnancy Test Midstream is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. Very low levels of hCG are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, [5] a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
3. This test reliably detects intact hCG up to 231522.5 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.
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.[6,7] 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.

【PERFORMANCE CHARACTERISTICS】

Accuracy and Sensitivity

A multi-center clinical evaluation was conducted comparing the results obtained using the hCG One Step Pregnancy Test Midstream to another commercially available urine membrane hCG test. The study included 150 urine specimens, and both assays identified 72 negative and 78 positive results. . The results demonstrated >99% overall accuracy of the hCG One Step Pregnancy Test Midstream when compared to the other urine membrane hCG test.

Specificity

The addition of LH (500mIU/mL), FSH (1,000mIU/mL) and TSH (1,000μIU/mL) to negative and positivespecimens showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20 mg/dL	Glucose	2 g/dL
Acetylsalicylic Acid	20 mg/dL	Hemoglobin	10mg/dL
Ascorbic Acid	20 mg/dL	Ampicillin	20 mg/dL
Atropine	20 mg/dL	Tetracycline	20mg/dl
Caffeine	20 mg/dL	Bilirubin	2 mg/dL
Gentisic Acid	20 mg/dL		

None of the substances at the concentration tested interfered in the assay.

【QUESTIONS & ANSWERS】

1.Q: How does the test work?

A: The hCG One Step Pregnancy 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.Q: How soon after I suspect that I am pregnant can I take the test?

A: 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.Q: Do I have to test with first morning urine?

A: 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.Q: How do I know that the test was run properly?

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

5.Q: What should I do if the result shows that I am pregnant?

A: 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.

6.Q: What should I do if the result shows that I am not pregnant?

A: 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】

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4.Lenton EA, LM Neal, R Sulaiman Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy, Fertil. Steril. 1982; 37(6): 773-778

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Index of Symbols

	Consult instructions for use		Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
IVD	In vitro diagnostic medical device		Use-by date		Do not re-use
	Temperature limit	LOT	Batch code	REF	Catalogue number
	Manufacturer		Date of Manufacture		Keep dry
	Keep away from sunlight		Do not use if package is damaged and consult	CE 0123	Meet the requirements of 98/79/EC Directive

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CE **0123**