



OneStep hCG Midstream Urine RapiCard™ InstaTest

REF 114360

PIC FT114360VV86

IVD See External Label 25 Tests

hCG Midstream Urine RapiCard™	
Principle	Chromatographic Immunoassay
Detection	Qualitative
Sensitivity	20 mIU/mL

PRODUCT FEATURES

- High Sensitivity and Specificity
- Built in Internal Controls
- Simplified Workflow, Non-invasive, and Safe
- Rapid and Faster Results

A rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in urine. For professional in vitro diagnostic use only.

INTENDED USE

The OneStep hCG Midstream Urine RapiCard™ InstaTest is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

SIGNIFICANCE AND SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum or plasma as early as 7 to 10 days after conception.^{1,2,3,4} hCG levels continue to rise very rapidly, frequently exceeding 100mIU/ml by the first missed menstrual period,^{2,3,4} and peaking in the 100,000-200,000mIU/ml range about 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum or plasma soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

The OneStep hCG Midstream Urine RapiCard™ InstaTest is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 20mIU/ml. The test utilizes a combination of antibodies including a monoclonal antibody to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the hCG Pregnancy Rapid Test Midstream shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

ASSAY PRINCIPLE

The OneStep hCG Midstream Urine RapiCard™ InstaTest is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. The test uses two lines to indicate results. 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.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

A urine specimen must 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 precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may 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 AND COMPONENTS

Materials provided with the test kit

- Test Midstream
- Package Insert

Materials required but not provided

- Timer
- Specimen Collection Container

ASSAY PROCEDURE

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

1. Remove the midstream from the foil pouch and test them immediately in one hour.
2. Take down the cap of the midstream, then urinate on it or place

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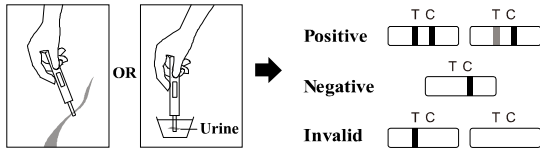
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the midstream into urine sample in a clean cup **at least 15 seconds.**

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



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 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 and correct procedural technique. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid.

LIMITATIONS OF THE PROCEDURE

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

- 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.
- 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.
- 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 reasons⁵, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
- 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.
- 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.
- 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.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

PRECAUTIONS

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

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

EXTRA INFORMATION

- How does the test midstream work?
The OneStep hCG Midstream Urine RapiCard™ InstaTest 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? 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.
- 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 OneStep hCG Midstream Urine RapiCard™




InstaTest 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 OneStep hCG Midstream Urine RapiCard™ InstaTest when compared to the other urine hCG test.

5. How sensitive is the test?
The OneStep hCG Midstream Urine RapiCard™ InstaTest detects hCG in urine at a concentration of 20 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 (20 mIU/mL hCG) specimens showed no cross-reactivity.
6. What should I do if the results 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 test result shows that I am not pregnant?
It means that no hCG has been deducted 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.

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016



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PIC	FT114360VV86
EU REP	AR Experts BV, Boeingavenue 201-219 1119 PD Schiphol-Rijk, The Netherlands info@ar-experts.eu

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