HCG Pregnancy Field Use Rapid Test Midstream

(Urine)

【INTENDED USE】

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

【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, which enables it an excellent marker for the early detection of pregnancy. The HCG Pregnancy Rapid Test Midstream is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 10mIU/ml. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the iCARE HCG Pregnancy Rapid Test Midstream shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

【TEST PRINCIPLE】

The iCARE HCG Pregnancy Rapid Test Midstream is a visual, rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine specimens to aid in the early detection of pregnancy. The rapid test midstream supports a membrane which has been coated with reagents necessary to detect the presence of hCG. The specimen is applied to the test midstream and reacts initially with the specific, anti-βhCG monoclonal antibody/colloidal gold conjugate on the test membrane. This mixture moves along the membrane, by capillary action, and reacts with a specific anti-hCG in the test region. If hCG is present in the specimen, the result is the formation of a colored band in the test region. If there is no hCG in the specimen, the area will remain white. The specimen continues to flow to the control region and forms a pink to purple color, indicating the test is working and the result is valid.

【MATERIALS PROVIDED】

Contents	1 Test/Kit	7 Tests/Kit	10 Tests/Kit	25 Tests/Kit	40 Tests/Kit
Test Midstream individually foil pouched with a desiccant	1	7	10	25	40
Package Insert	1	1	1	1	1

【MATERIALS REQUIRED BUT NOT PROVIDED】

Timer, Specimen Collection Container

【STORAGE AND STABILITY】

1. Store as packaged at room temperature or refrigerated (2-30℃).
2. The test is stable through the expiration date printed on the sealed pouch and outer package.
3. DO NOT FREEZE.

【WARNINGS AND PRECAUTIONS】

1. These instructions must be carefully read and strictly followed to achieve accurate results before performing the test.
2. For in vitro diagnostic use only. Do not use the kit beyond the expiration date printed on the outer package.
3. Do not open foil pouch until ready to perform the test.
4. Handle all specimens as potentially hazardous and handle in the same manner as an infectious agent.
5. Use appropriate precautions in the collection, storage, handling and disposal of specimens and used kit contents.
6. Dispose of containers and used contents according to local laws and regulations.

【TEST PROCEDURES】

For direct test

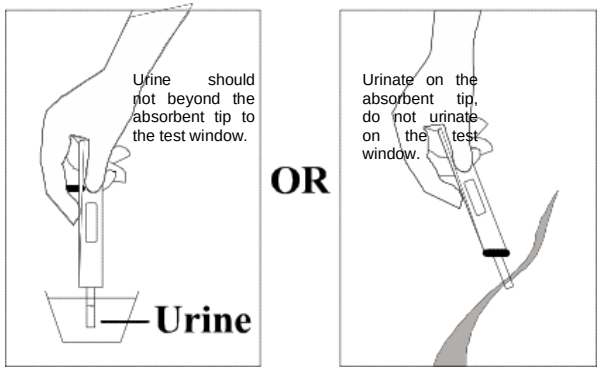
1. Remove the cover of the test midstream.
2. Put the absorbent tip of the test midstream directly in urine stream for at least 7-10 seconds to allow the specimen into the test midstream.

   Note: Do not urinate on the test window.
3. Take out the test midstream from the urine and cover the test midstream.
4. Place the test midstream horizontally with the test window facing upwards, and start the timer.
5. Read result at 3 minutes after the addition of specimens. Do not read result after 10 minutes.

For collected urine

1. Remove the cover of the test midstream.
2. Insert the absorbent tip vertically into the disposable plastic cup containing urine (at least 2ml) at least 10 seconds. During the period, the absorbent tip can be changed slightly to suck up the liquid.

   Note: Do not let the urine go beyond the absorbent tip to the test window.
3. When the liquid appears in the test window, take out the test midstream from the urine and cover the test midstream.
4. Place the test midstream horizontally with the test window facing upwards, and start the timer.
5. Read result at 3 minutes after the addition of specimens. Do not interpret the result after 10 minutes.



【INTERPRETATION OF TEST RESULTS】

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
***NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【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 indicates sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If a background color appears in the test result window and interferes with the ability to read the test result, the result may be invalid. It is recommended that a positive hCG control (containing 10-250mIU/ml hCG) and a negative hCG control (containing "0"mIU/ml hCG) be evaluated to verify proper test performance when receiving a new shipment of tests.

【EXPECTED VALUES】

Results of tests on healthy, non-pregnant women are negative using the iCARE HCG Pregnancy Rapid Test Midstream. Most pregnant women have urine hCG levels of 100 mIU/ml or greater the day of the first missed menstrual period. This level of hCG is clearly detected using this test. Peak hCG levels are reached about 8 weeks later. Following delivery, hCG levels rapidly decrease and usually return to non- pregnant levels within days. Elevated hCG has also been seen in women with choriocarcinoma and non- trophoblastic neoplasm. The iCARE HCG Pregnancy Rapid Test Midstream has a sensitivity of 10mIU/ml, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

【PERFORMANCE CHARACTERISTICS】

Sensitivity

The iCARE HCG Pregnancy Rapid Test Midstream detects hCG at the concentration of 10mIU/ml or greater. The test has been standardized to the World Health Organization International Standard. A total of 180
tests were performed, at the three hCG concentrations. hCG specimens were prepared at the following concentrations using hCG free urine; 0 mIU/ml, 10mIU/ml and 600,000 mIU/ml. All tests were negative with the hCG negative urine and positive with the 10mIU/ml and 600,000 mIU/ml specimens.

Hook Effect

There was no hook effect at hCG levels up to 600,000 mIU/ml in urine.

Accuracy

A multi-center clinical evaluation was conducted comparing the test results obtained using the iCARE HCG Pregnancy Rapid Test Midstream to another commercially available urine membrane hCG test. The study included 127 urine specimens: both assays identified 61 negative and 66 positive results. The results demonstrated a >99% overall accuracy of the test when compared to the other urine membrane hCG test.

hCG Reference Method (Urine)

Method		Other hCG Rapid Test		
	Results	**Positive**	**Negative**	**Total**
ICARE HCG Pregnancy Rapid Test Midstream	**Positive**	66	0	66
	Negative	0	61	61
	Total	66	61	127
Sensitivity: > 99.9% (94.50%-100%), 95% CI*				
Specificity: > 99.9% (94.08%-100%), 95% CI*				
Accuracy: > 99.9% (97.06%-100%), 95% CI* * 95% Confidence Intervals				

Specificity

The specificity of the test was determined from cross reaction studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). Specimens containing 300 mIU/ml hLH, 1000 mIU/ml hFSH and 1000 mIU/ml hTSH all gave negative results.

Interfering Substance

Potentially interfering substances as listed below were added to hCG negative and positive specimens. No interference was found with any of the substances at the following concentrations:

Acetaminophen	20 mg/dL	Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Atropine	20 mg/dL
Caffeine	20 mg/dL	Gentisic Acid	20 mg/dL
Glucose	2 g/dL	Hemoglobin	1 mg/dL
Bilirubin	2 mg/dL		

【LIMITATIONS 】

1. The iCARE HCG Pregnancy Rapid Test Midstream is a qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. This test may produce false positive results. A number of conditions, other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasm cause elevated levels of hCG[5,6]. These conditions should be considered with appropriate clinical evidence.
3. This test may produce false negative results. False negative results may occur when the levels of hCG are below the detection limit of the test. If pregnancy is still suspected, a first morning urine should be obtained 24-48 hours later and retested. In case pregnancy is suspected and the test continues to produce negative results, consult a physician for further diagnosis.
4. A dilute urine specimen of a very low specific gravity may not contain sufficient levels of hCG to give a positive result. If pregnancy is still suspected, a first morning urine should be obtained 24-48 hours later and retested.
5. Very low levels of hCG (less than 50 mIU/ml) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons[7], a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
6. Such specimens may cause false positive or false negative results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

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