hCG Pregnancy Rapid Test Cassette(Serum /Plasma/Urine)
Package Insert（English）

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

【INTENDED USE】

The hCG Pregnancy Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum or plasma 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, make it an excellent marker for the early detection of pregnancy.

The hCG Pregnancy Rapid Test Cassette is a rapid test that qualitatively detects the presence of hCG in urine or serum or plasma specimen at the sensitivity of 25mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine or serum or plasma. At the level of claimed sensitivity, the hCG Pregnancy Rapid Test Cassette shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

【PRINCIPLE】

The hCG Pregnancy Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum or plasma 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 control line is composed of goat polyclonal antibodies and colloidal gold particles. The assay is conducted by immersing the test cassette in a urine or serum or plasma specimen and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-hCG-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【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.

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

【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 or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【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.

Serum or plasma Assay

Blood should be collected aseptically into a clean tube without anticoagulants (Serum) or with anticoagulants (Plasma) . Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.

Specimen Storage

Urine or serum or plasma specimens may be stored at 2-8℃ for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed before testing.

【MATERIALS 】

Materials provided

Test cassettes　Droppers　Package insert

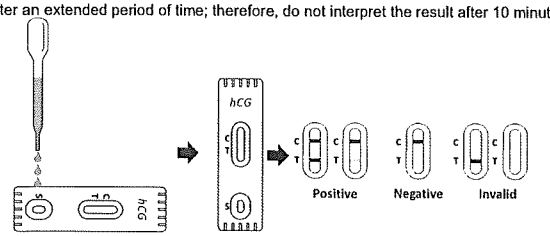
Materials required but not provided

Specimen collection containers　Timer

【DIRECTIONS FOR USE】

1. Bring the pouch to room temperature (15-30℃) before opening it. Remove the cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine or serum or plasma (approximately 120ul)** to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line(s) to appear. **Read the result at 3 minutes when testing a urine specimen, or at 5 minutes when testing a serum or plasma specimen.**

NOTE: A low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

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.

【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. 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. It is recommended that a positive hCG control (containing 25-250mIU/mL hCG) and a negative hCG control (containing "0"mIU/mL hCG) be evaluated to verify proper test performance when a new shipment of tests is received.

【LIMITATIONS】

1. The hCG Pregnancy Rapid Test Cassette 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 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 50 mIU/mL) are present in urine and serum or plasma specimen 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 or serum or plasma 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.[6,7] Therefore, the presence of hCG in urine or serum or plasma specimens 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. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
7. 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.

【EXPECT VALUE】

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum or plasma specimens. The amount of hCG will vary greatly with gestational age and between individuals. The hCG Pregnancy Rapid Test Cassette (Urine/serum or plasma) has a sensitivity of 25mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the hCG Pregnancy Rapid Test Cassette to another commercially available urine and serum or plasma hCG Rapid test. The urine study included 413 specimens, and both assays identified 296 negative and 117 positive results. The serum study included 200 specimens, and both assays identified 141 negative and 59 positive results. The plasma study included 200 specimens, and both assays identified 141 negative and 59 positive results. The results demonstrated a >99% overall accuracy of the hCG Pregnancy Rapid Test Cassette when compared to the other urine and serum or plasma hCG Rapid test.

hCG Reference Method (Urine)

Method		Other hCG Rapid Test		Total Results
hCG Pregnancy Rapid Test Cassette	Results	Positive	Negative	
	Positive	117	0	117
	Negative	0	296	296
Total Results		117	296	413

Sensitivity: > 99.9% (97.5%~100%)*　Specificity: > 99.9%(99.0%~100%)*

Accuracy: > 99.9 %(99.3%~100%) *　* 95% Confidence Intervals

hCG Reference Method(Serum)

Method		Other hCG Rapid Test		Total Results
hCG Pregnancy Rapid Test Cassette	Results	Positive	Negative	
	Positive	59	0	59
	Negative	0	141	141
Total Results		59	141	200

Sensitivity: > 99.9% (95.0%~100%)*　Specificity: > 99.9%(97.9%~100%)*

Accuracy: > 99.9%(98.5%~100%) *　* 95% Confidence Intervals

hCG Reference Method (Plasma)

Method		Other hCG Rapid Test		Total Results
hCG Pregnancy Rapid Test Cassette	Results	Positive	Negative	
	Positive	59	0	59
	Negative	0	141	141
Total Results		59	141	200

Sensitivity: > 99.9% (95.0%~100%)*　Specificity: > 99.9%(97.9%~100%)*

Accuracy: > 99.9%(98.5%~100%) *　* 95% Confidence Intervals

Sensitivity and Cross-Reactivity

The HCG Pregnancy Rapid Test Cassette detects hCG at a concentration of 25mIU/mL or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (300mIU/mL), FSH (1,000mIU/mL), and TSH (1,000μIU/mL) to negative (0mIU/mL hCG) and positive (25mIU/mL hCG) specimens showed no cross-reactivity.

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens containing 25mIU/ml, 100mIU/ml, 250mIU/ml and 0mIU/ml of HCG. The negative and positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by using the same three specimens of 25mIU/ml, 100mIU/ml, 250mIu/ml and 0mIU/ml of HCG in 10 independent assays. Three different lots of the HCG Pregnancy Rapid Test Cassette have been tested. The specimens were correctly identified 100% of the time.

Interfering Substance

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

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Glucose	2 g/dL
Atropine	20 mg/dL	Hemoglobin	1 mg/dL
Bilirubin(urine)	2 mg/dL	Bilirubin(serum or plasma)	40 mg/dL
Triglycerides (serum or plasma)	1,200 mg/dL		

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

【BIBLIOGRAPHY】

1. Batzer FR. Hormonal evaluation of early pregnancy, Fertil. Steril. 1980; 34(1): 1-13
2. Catt KJ, ML Dufau, JL Vaitukaitis Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte, J. Clin. Endocrinol. Metab. 1975; 40(3): 537-540
3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade Serum or plasma human chorionic gonadotropin levels throughout normal pregnancy, Am. J. Obstet. Gynecol. 1976; 126(6): 678-681
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
5. 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
6. Dawood MY, BB Saxena, R Landesman Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma, Obstet. Gynecol. 1977; 50(2): 172-181
7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross Ectopic production of human chorionic gonadotropin by neoplasms, Ann. Intern Med. 1973; 78(1): 39-45.

Number: RP5020401
Effective date: 2016-02-26