Sirin Diagnostics HCG Pregnancy Test (Cassette)

For in vitro diagnostic use only Serum/Urine

INTENDED USE

HCG Pregnancy Test is a immunoassay made for the rapid, visual and qualitative determination of human chorionic gonadotropin(HCG) in serum or urine specimen to aid in the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (HCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In normal pregnancy, HCG can be detected in serum as early as 7 days following conception. The concentration of HCG continues to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 100,000-200,000 mIU/mL range by 10-12 weeks into pregnancy. The appearance of HCG soon after conception and its subsequent rise in concentration during early gestational growth make it an excellent marker for the early detection of pregnancy.

PRINCIPLE

The HCG Pregnancy Test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of HCG in serum or urine. The membrane is pre-coated with anti-alpha HCG capture antibody on the test line region and goat anti-mouse on the control line region. During testing, the serum or urine specimen is allowed to react with the colored conjugate (mouse anti-beta HCG monoclonal antibody-colloidal gold conjugate), which has been predried on the test strip. The mixture then moves upward on the membrane chromatographically by capillary action. For a positive result, a pink-colored line with the specific antibody-HCG-colored conjugate complex will form in the test line region of the membrane. Absence of this pink-colored line in the test line region indicates a negative result. Regardless of the presence of HCG, as the mixture continues to move across the membrane to the immobilized goat anti-mouse, a pink-col- ored line at the control line region will always appear. The presence of this pink-colored line serves as: 1) verification that sufficient volume is added. 2) that proper flow is obtained, and 3) as a control for the reagents.

PRECAUTIONS

1. Read instruction for use carefully before performing this test.
2. Do not use the test kit beyond the expiration date.
3. The test device should remain in the sealed pouch until use.
4. Do not reuse the device. Discard it in the dustbin after use.
5. Treat serum or urine specimen and used device as if they were potentially infectious.

REAGENTS

The test strip contains an anti-alpha HCG capture antibody coated membrane and colloidal gold particles coated with mouse anti-beta HCG monoclonal antibody.

STORAGE AND STABILITY

The test device can be stored at 2-30℃ in the sealed pouch. The test device is stable through the expiration date printed on the sealed pouch. DO NOT FREEZE.

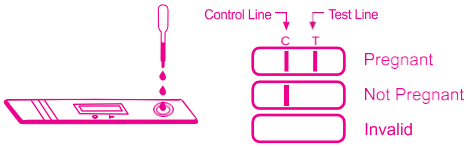
SPECIMEN COLLECTION

1)[Serum] Centrifuge whole blood to get serum specimen. If serum is not tested immediately, it should be refrigerated at 2-8 ℃. For storage periods greater than three days, freezing is recommended . They should be brought to room temperature priorto use. Serum containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

2) [Urine] Use a dry, clean container to collect urine. Urine specimen collected at any time of day may be used, however, the first morning urine is preferred since it generally contains the highest concentration of HCG.

TEST PROCEDURE

Test device and specimen should be brought to room temperature (15-30) prior to testing. Do not open pouches until ready to perform the assay.



1. Remove the test device from the sealed pouch, lay it flatly on a non- absorbent clean surface and use it as soon as possible.
2. For only serum specimen, draw and dispense 3 drops of serum.
   For only urine specimen, dispense 3 drops of urine into the sample well.
3. Wait for pink-colored lines to appear. Read result within 5~8 minutes. Do not read result after 10 minutes.

INTERPRETATION OF RESULTS

PREGNANT:Two distinct pink-colored lines appear, one in the test region (T) and one in the control region(C). NOTE: **NOTE** The intensity of the pink color in the test region (T) may vary depending on the concentration of HCG present in the specimen. Therefore, any shade of pink color in the test region (T) should be considered positive.

NOT PREGNANT: Only one pink-colored line appears in the control region(C). No apparent pink line appears in the test region (T). INVALID: Control Line fails to appear.

NOTE : 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, please contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing on the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive reagents. A clear background in the membrane is considered an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will clear to give a discernible result.

LIMITATION

1. Excessive fluid intake should be avoided before testing. If the specimen is too dilute, it may not contain representative levels of HCG.
2. A number of conditions other than pregnancy, including trophoblastic disease and certain nontrophoblastic neoplasms such as testicular tumors, prostate cancer, breast cancer and lung cancer cause elevated levels of HCG and may give a false “Pregnant” result.
3. Fertility drugs containing HCG can give false “Pregnant” result.
4. Very low levels of HCG (less than 50 mIU/mL) are present in the specimen shortly after implantation. A test result is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
5. 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.

Healthy men and healthy non-pregnant women do not have detectable HCG by the HCG Pregnancy Test. However, healthy pregnant women have HCG present in their urine and serum specimens. The amount of HCG will vary greatly with gestational age and between individuals. The HCG Pregnancy Test has a sensitivity of 25mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity: No less than 25mIU/ml

Analytical Specificity: The test results show negative for the 500mIU/ml hLH, 1000mIU/ml hFSH and 1000μIU/ml hTSH specimens.

Diagnostic Sensitivity and Diagnostic Specificy: This HCG Pregnancy Test detects HCG at a concentration of 25mIU/ml or greater. 900 known negative urine/serum specimens were equally divided into 6 groups. Each group of specimens (150) were spiked with HCG to the concentration of 0mIU/ml, 5mIU/ml, 15mIU/ml, 25mIU/ml, 50mIU/ml and 5IU/ml separately, calibrated against WHO 4th international standard. Each group of specimen was tested with HCG Pregnancy Test. The results from this study gave >99% agreement with the expected results.

Result	0mIU/ml	5mIU/ml	15mIU/ml	25mIU/ml	50mIU/ml	5IU/ml	Total
Positive	0	0	0	150	150	150	450
Negative	150	150	150	0	0	0	450
Total	150	150	150	150	150	150	900

Diagnostic sensitivity=100% (450/450)
Diagnostic specificity=100% (450/450)

Interference Testing: The following substances were added in HCG free and HCG spiked urine/serum specimens. None of the substances at concentration tested interfered in the assay. For example:

Acetaminophen	0.2mg/ml	Acetylsalicylic Acid	0.2mg/ml
Ascorbic Acid	0.2mg/ml	Atropine	0.2mg/ml
Caffeine	0.2mg/ml	Gentesic Acid	0.2mg/ml
Glucose	20mg/ml	Hemoglobin	10μg/ml
Tetracycline	0.2mg/ml		

INDEX OF SYMBOLS

	Consult instructions for use		Use-by date
IVD	In vitro diagnostic medical device	LOT	Batch code
	Store at 2-30℃		Manufacturer
	Do not re-use	EC REP	Authorized representative in the European Community
	Date of manufacture		

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