

HCG Rapid Test Device

Immuno-chromatographic rapid test device for qualitative detection of human chorionic gonadotropin in urine

Catalog #:ID1006

INTRODUCTION

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 serum and urine as early as 7 to 10 days after conception. hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/ml by the first missed menstrual period, and peaking in the 100-200 mIU/ml range about 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum 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-Card is a rapid serum and urine test to qualitatively detect the presence of hCG in urine specimens 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. At the level of claimed sensitivity, hCG-Card shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at physiological levels.

SUMMARY AND PRINCIPLE OF THE TEST

The hCG-Card is a qualitative, solid phase, two-site sandwich immunoassay for the detection of human chorionic gonadotropin (hCG) in serum/urine. The membrane is pre-coated with anti-hCG antibodies on the test band region and anti-mouse antibodies on the control band region. During testing, the serum or urine sample reacts with the colored conjugate (mouse anti-hCG antibody colloidal gold conjugate) which has been pre-coated on the test strip. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hCG antibodies on the membrane and generate a red band. Presence of the red band indicates a positive result, while its absence indicates a negative result. Regardless of the presence of hCG, as the mixture continues to migrate across the membrane to the immobilized goat anti-mouse region, a red band at the control band region will always appear. The presence of this red band serves as verification for sufficient sample volume and proper flow and as a control for the reagents.

REAGENTS AND MATERIALS

hCG-Card	50
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PRECAUTION FOR USERS

- For in-vitro diagnostic use only.
- Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
- Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
- Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
- Avoid contact between hands and eyes or nose during specimen collection and testing.

SPECIMEN COLLECTION

The urine specimen must be collected in a clean, dry plastic or glass container. The first morning urine is preferred since it generally contains the highest concentration of hCG. However, urine collected at any time of day may be used. Urine samples exhibiting visible precipitates should be centrifuged, or allowed to settle to obtain clear supernatant for testing. Urine specimens may be stored at 2-8 °C.

No special preparation of the patient is required prior to blood collection. Blood should be collected by approved medical techniques. Remove serum or plasma from the clot or blood cells as soon as possible to avoid hemolysis. Grossly hemolytic, lipidic or turbid samples should not be used. Plasma samples containing EDTA, heparin or oxalate may interfere with test procedures and should be avoided. Specimen with extensive particulate should be clarified by centrifugation prior to use. Covered specimens may be stored for up to 48 hours at 2°-8°C prior to assaying. Specimens held for a longer time can be frozen at -20°C for mix prior to testing. Avoid repeated freeze thaw.

STORAGE OF TEST KIT

The hCG-Card can be stored at any temperature between 4-30°C. **Do not freeze.** The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked.

TEST PROCEDURE

- When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.
- Draw 4-5 drops sample into the pipette, and dispense it into the sample well on the cassette.
- Wait 3-5 minutes and read results. Do not read results after 5 minutes.

INTERPRETATION OF RESULTS



Negative: Only one colored band appears on the control region. No apparent band on the test region.

Positive: In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.

Invalid: A total absence of color in both regions is an indication of procedure error and/or that test reagent deterioration has occurred.

LIMITATIONS OF THE ASSAY

Very dilute urine specimens as indicated by low specific gravity may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be obtained 48-72 hours later and tested. Very low levels of hCG (less than 50m IU/ml) are present in urine 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 interpreted in conjunction with other clinical and laboratory data. 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 (8-9). Therefore, the presence of hCG in urine as determined by using One Step Pregnancy Test should not be used to diagnose pregnancy unless these conditions have been ruled out. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Urine and serum hCG concentration of pregnant women rise very rapidly after implantation, reaching a peak concentration in excess of 200 mIU/ml about 2-3 months after the last menstrual period (3). hCG-Card has a sensitivity of 25 mIU/ml and is capable of detecting pregnancy as early as 1 day after the first missed menses. Reportedly, a level of 25 mIU/ml or more, is present 7-10 days after conception or 4-5 days prior to the first missed menses (3). Test results which appear as a very light line in the test region are not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urine specimen be obtained after 48-72 hours and tested again. Negative test results in patients suspected to be pregnant should be re-tested with the first morning specimen obtained 48-72 hours later.

PERFORMANCE

Sensitivity

The analytical sensitivity of hCG-Card is 25mIU/ml. The sensitivity was established by repetitive testing of samples containing 25mIU/ml hCG during a period of several weeks.

Specificity

The specificity of the hCG-Card was determined from cross-reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). Negative results were obtained from all tests conducted with 280 mIU/ml hLH, 500 mIU/ml hFSH and 1000 µIU/ml hTSH.

Precision

A study was conducted which consisted of performing a series of replicate assays using 3 different concentration of hCG in serum and urine. The results were as follows:

hCG Conc. mIU/ml	Pos.	Neg.
0	0	50

25	50	0
100	50	0

RELATED READING MATERIALS

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In vitro diagnostic device



Lot code



Consult instructions for use



Catalogue number



Keep dry



Contains sufficient for <n> tests



Temperature limitation



Manufacturer



Use by



Do not use if package damaged