LIMITATIONS

1. In addition to pregnancy, hCG has been found in patients with both gestational and non-gestational trophoblastic disease. Since the hCG of trophoblastic neoplasma is similar to that found in pregnancy, these conditions, which include choriocarcinoma and hydatichiform mole should be ruled out before a diagnosis of pregnancy is reached.
2. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
3. A very early pregnancy containing an extremely low hCG concentration or urine sample is too dilute (i.e. with low specific gravity) and may not contain a representative level of hCG. This can produce false negative results. In these cases, a second specimen should be obtained at least 24-48 hours later and retested.
4. hCG levels may remain detected for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion or therapeutic abortion.
5. Occasionally, specimen containing less than 25 mIU/ml of urine may also yield positive results.
6. In cases where very high levels of hCG are present, a false negative result can occur due to the prozone effect. If pregnancy is still suspected, simply dilute specimen 1:1 with deionized water and retest.
7. As with all diagnostic test, clinical diagnosis should not be based on a single test but should only be made in light of other clinical information and results.
8. Do not use specimen if blood is present as this can produce false results. Even trace amount of blood is undesirable and a new specimen should be obtained.

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URINE PREGNANCY CARD TEST

INTENDED USE

The Pulse Pregnancy Card Test (PREGCARD Test) is a rapid qualitative one-step assay for the detection of human chorionic gonadotropin (hCG) in urine specimens.

SUMMARY & EXPLANATION

Human chorionic gonadotropin is a glycoprotein hormone secreted by the developing placenta shortly after fertilization[1-4]. In normal pregnancy, hCG can be detected in serum as early as 7 days after conception. At the time of the first missed menstrual period, serum hCG levels reached 100 mIU/ml with peak levels of 100,000 to 200,000 mIU/ml[1-5] observed at the end of the first trimester. The presence of hCG soon after conception and its subsequent increase in concentration during early gestational growth make it an ideal marker for the early detection of pregnancy. The PREGCARD Test is a rapid test to detect hCG at levels as low as 25mIU/ml in urine specimen as an early indication of pregnancy. Elevated hCG levels comparable to those observed in early pregnancy may also be associated with trophoblastic or non-trophoblastic neoplasma[6] such as hydatichiform mole and choriocarcinoma and other situations as indicated in the Limitation Section.

PRINCIPLES

The PREGCARD Test is based on a two-site sandwich immunoassay [7-8] intended for the determination of hCG in urine. The membrane was pre-coated with goat anti-hCG on the Test Band Region and goat anti-mouse on the Control Region. In performing this test, the patient urine specimen is allowed to react with the coloured conjugate (mouse anti-hCG monoclonal antibody colloidal gold conjugate) which was pre-dried on the strip. The mixture migrates in an upward direction on the strip through capillary action. In a positive result, two distinct pink-rose colour bands will be visible, one in the Test Region and one in the Control Region. To serve as a procedural control, a pink-rose colour band is always visible at the Control Region and this colour band also signifies a negative result. The immunological specificity of the test virtually eliminates cross reactivity interference from the structurally related glycoprotein hormones such as hFSH, hLH and hTSH at physiological levels.

MATERIALS SUPPLIED

Test Cards: Sufficient PREGCARD Tests are supplied as individual packages with desiccant and pipet.

STORAGE & STABILITY

The PREGCARD Test should be stored at 2-30 Degree Celsius when not in use. DO NOT FREEZE. PREGCARD Tests are stable up to the indicated expiry date. Heat, moisture and direct sunlight must be avoided to maintain stability.

PRECAUTIONS

This product is for In Vitro Diagnostic Use Only. Read instructions before use. Do not use product beyond its expiry date.

SPECIMEN COLLECTION

The urine specimen must be collected in a clean dry container without preservatives. For optimum results, a first morning urine specimen is preferred since it contains the highest concentration of hCG. Urine specimens may be refrigerated (2 – 8 Degree Celsius) and stored up to 72 hours prior to testing. If samples are refrigerated, they must be warmed to room temperature before performing test. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle and only use the clear supernatant for testing. Specimen containing even traces of blood should not be used.

NOTE: Handle all specimens as potentially infectious and according to Good Laboratory Practice.

PROCEDURE

PREGCARD Tests, specimen and other reference materials should be at room temperature prior to performing test.

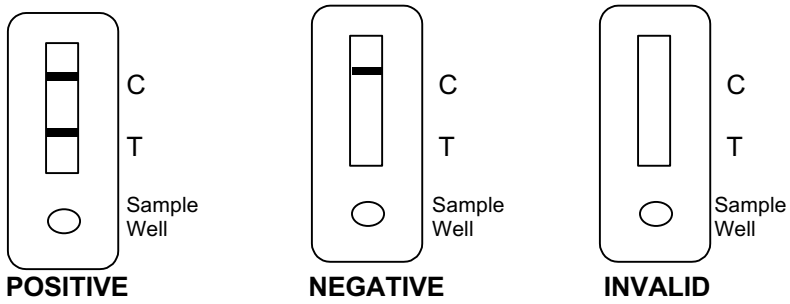
1. Remove PREGCARD Tests from its protective pouch.
2. Label PREGCARD Test with proper patient information.
3. Add three (3) drops of urine into the Sample Well with the pipet supplied. Hold the pipet in a vertical position. Use a separate pipet for each specimen.
4. Results will usually appear in 10-30 seconds but a waiting time up to 5 minutes is required to confirm negative or weak positive results. DO NOT interpret results after 10 minutes.

RESULTS

Positive: In addition to the Control Band, a second Pink-rose colour band appears in the Test (T) Region.

Negative: Only One Pink-rose colour band in the Control (C) Region.

Invalid: No colour bands or other observation that deviates from the expected results. Repeat Test.



QUALITY CONTROL

Fresh samples from known pregnant and non-pregnant patients may be used as controls in verifying the performance of the test. Alternatively, human urine controls with positive hCG levels and negative controls with no detectable hCG levels are available from Pulse Scientific. It is recommended that the use of controls on a daily basis be followed to ensure proper kit performance.

PERFORMANCE CHARACTERISTICS

Sensitivity & Specificity

The PREGCARD Test has been standardized according to the World Health Organization International Reference Preparation (WHO 1st IRP or WHO 3rd IRP). Specificity has been established by cross reaction studies with Luteinizing Hormone (hLH, 300 mIU/ml), Follicle Stimulating Hormone (hFSH, 1000 mIU/ml) and Thyroid Stimulating Hormone (hTSH, 1000 mIU/ml) and all test results indicated no interference.

Interferences

Potentially interfering substances were added to urine which had hCG levels of 0 and 50 mIU/ml. In each case, no interference with the PULSE PREGCARD was observed.

Acetaminophen	20 mg/ml	Acetylsalicyclic Acid	20 mg/ml
Ascorbic Acid	20 mg/ml	Atropine	20 mg/ml
Caffeine	20 mg/ml	Gentesic Acid	20 mg/ml
Glucose	2 g/dL	Hemoglobin	1 mg/dL