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SUBJECT: Pregnancy Test, Immunocard Stat hCG Combo Rapid Test

1. PRINCIPLE:

The Immunocard Stat hCG Combo is a chromatographic immunoassay for the rapid qualitative determination of hCG in urine or serum. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to detect elevated levels of hCG. The assay is conducted by adding serum or urine specimen to the well of the test cassette and observing the formation of colored lines. The specimen migrates by capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific colored antibody conjugates and form a solid, black line at the test line region of the membrane. Absence of this line suggests a negative result. To serve as a procedural control, a solid, black line will always appear at the control line region if the test has been performed properly.

2. CLINICAL SIGNIFICANCE:

Human chorionic gonadotropin is a hormone secreted by the developing placenta shortly after fertilization. The appearance and rapid rise in the concentration of hCG in the mother's serum make it an excellent marker for pregnancy.
A number of conditions other than pregnancy can cause an elevated level of hCG (see interfering substances); therefore the presence of hCG in a serum or urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.

3. SPECIMEN:

A. COLLECTION AND PROCESSING:

Urine samples: The specimen must be collected in a clean, dry container. Specimens collected at any time of day may be used; however, the first morning urine generally contains the highest concentration of hormone. Urine specimens may be refrigerated at 2-8C and stored for up to 48 hours prior to testing. If samples are refrigerated, they must be equilibrated to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle, prior to testing.
Serum samples: No special preparation of the patient serum is required. Serum not assayed immediately must be stored refrigerated 2-8C for up to 48 hours or frozen for up to 3 months. Do not freeze and thaw sample repeatedly. Frozen samples should be mixed well before testing. Grossly hemolyzed samples should not be used

B. REJECTION:

Grossly bloody or cloudy urines should be centrifuged prior to testing. Grossly hemolyzed serum samples should be rejected. All mislabeled or incompletely labeled specimens must be rejected

C. STORAGE AND PRESERVATION:

Urine samples may be refrigerated at 2-8C and stored for up to 72 hours. Bring to room temp. Before testing.
Room temperature stability for urine hCG is 8 hours.
Serum samples may be refrigerated for up to 48 hours or frozen for up to 3 months.
*Note: Plasma specimens are not suitable for testing.

4. REAGENTS, STANDARDS, AND CONTROLS:

A. PREPARATION:

The test kit is stored at room temperature for the duration of the shelf-life. The test device should remain sealed in the pouch until ready for use.
The kit contains 25 individually packaged test cassettes, each containing one disposable specimen dropper and one directional insert.

B. CONTROL PROCEDURE:

A procedural control is included in the test. A solid, black line appearing on the control region is considered an internal positive procedural control, indicating proper performance. A clear background in the result window is considered an internal negative procedural control. If the test is working properly and has been performed correctly, the background will clear giving a distinct result.
A external positive and negative control must be tested with each new box opened.

5. EQUIPMENT:

n/a

6. PROCEDURE:

A. PERFORMANCE:

1. Test devices, samples, and controls should be at room temperature prior to testing. Do not open pouches until ready to perform the assay.
2. Remove the test device from its pouch. Label the device with patient or sample number. Place on a clean flat surface.
3. Fill the pipette to the line with sample and dispense the sample into the sample well of the test device.
4. Set a timer for 3 minutes for urine or 5 minutes for serum.
5. Read the results at 3 minutes for urine or 5 minutes for serum.

B. CALCULATIONS:

n/a

C. INTERPRETATION OF RESULTS:

Positive:

Two distinct Solid black lines appear. One in the control region (C) and another in the test region (T) The intensity on the test line may vary depending on the concentration of the hCG present. However, neither the quantitative value nor the rate of increase in hCG can be determined by this test.

Negative:

Only one line appears in the control region (C). No line appears in the test region.

Invalid:

Absence of a solid line in the control region is an indication of procedural error or that test reagent deterioration might have occurred. Repeat test with a new device and read for presence of a colored control line. If problem persists, call POCT office or Technical Services at 1-800-343-3858. Do NOT report the result.

7. QC PERFORMANCE POLICY: Upon opening a new box of test kits, the testing personnel will perform QC testing using external controls and record results on the Kit test log sheet and in the LIS. The kit box must be marked with date of testing and initials of personnel performing the QC testing indicating QC acceptable.

A. CALIBRATION AND CALIBRATION VERIFICATION

n/a

B. FAILURE/REMEDIAL ACTION:

Repeat test with a new device and read for presence of a colored control line. If problem persists, call POCT or NVML technical staff.Call technical service at 1-866-211-7853 for additional help.

8. EXPEXCTED RESULTS:

A. REPORTABLE RANGE:

Results are reported as negative or positive. A positive result represents a concentration of hCG greater than 20 U/ml in urine and greater than 10 U/ml in serum.

B. REFERENCE RANGE:

NEGATIVE Specimens from healthy men and healthy nonpregnant women should not contain detectable levels of hCG. Other conditions may exist which cause positive results. See interfering substances section.

C. CRITICALVALUES:

n/a

9. REPORTING RESULTS:

A. NORMAL VALUES:
Report as positive or negative

10. PROCEDURAL NOTES:

A. BACKUP FOR INOPERABLE SYSTEM
Send properly labeled specimen to main lab. Order in LIS.

11. LIMITATIONS AND INTERFERRING SUBSTANCES:

a. Very dilute urine 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.
b. 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 serum or urine specimen should be collected 48 hours later and tested.
c. Very low levels of hCG (less than 50 mIU/ml) are present in serum and urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning serum or urine specimen collected 48 hours later.
d. 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. Therefore, the presence of hCG in a serum or urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
e. 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 either false positive or false negative results.
f. This test provides only 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.

12. METHOD VALIDATION:

December 2012.

13. REFERENCES:

Meridian Immunocard Stat hCG package insert, number 755425, hCG Combo Rapid Test

Policy Approval:

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