Alere hCG Combo
Department of Clinical Laboratories
The Ohio State University Wexner Medical Center

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Point of Care Testing	Procedure	10/1/2016	POC-76 Revision 2

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Approval and Acknowledgements
Refer to QPulse system and Document Details report for laboratory directors(s)' electronic signature approval, employee acknowledgment and effective date.

1. PRINCIPLE:

1.1. Human chorionic gonadotropin is a hormone normally produced by the placenta. Since hCG is present in the serum and urine of pregnant women, it is an excellent marker for confirming pregnancy.

1.2. The Alere™ hCG Cassette (20 mIU/mL/ 10 mIU/mL) test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding specimen to the well of the test cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

1.3. Positive specimens react with the specific colored antibody conjugates and 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 at the control line region if the test has been performed properly.

2. SCOPE OF DOCUMENT

2.1. This document applies to all point of care locations, pre-procdure testing urine hCG with the Alere hCG Combo Cassette.

3. RESPONSIBILITY

3.1. The coordinators and manager are responsible for maintaining this document and ensuring biennial review. The laboratory division directors over each urine hCG CLIA testing site are responsible for approving all changes, and reviewing biennial when there are no revisions. The laboratory medical director is responsible for establishing and approving all changes before activating document

3.2. The testing personnel are required to take a color blindness test with the initial training and annual competency

4. SPECIMEN COLLECTION:

4.1. Verify patient identification using at least 2 identifiers.

4.1.1. Patients with an identification bracelet: double-check name and medical record number

4.1.2. If the patient is able, verify the patient's identity by asking them to state their name. Compare with name on identification bracelet.

4.1.3. Match the patient name and medical record number on the identification bracelet with the tube labels or request form

4.2. Specimen Type

4.2.1. Collect urine specimens in a clean dry container, label container.

4.2.2. For optimal results, it is best to test the first urine voided in the morning because it contains the greatest concentration of hCG. Urine collected anytime during the day can be used.

4.2.3. Urine specimens may be stored for 2 hours at room temperature (15-30^{o}C) or up to 48 hours refrigerated (2-8^{o}C).

4.3. Collect at least 1mL of urine to ensure proper amount of specimen for testing.

4.4. Do not use urine samples containing blood or unusual color (orange/green) to run this test. Any unusual color will make it difficult to detect a weak positive result.

4.5. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.

5. REAGENTS/SUPPLIES:

5.1. Each Alere hCG Combo test kit contains:

5.1.1. Test cassettes

5.1.1.1. Contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated to the membrane,

5.1.2. Disposable pipettes

5.1.3. Directional insert.

5.2. WARNINGS AND PRECAUTIONS:
5.2.1. For professional in vitro diagnostic use only.
5.2.2. The test cassette should remain in the sealed pouch until use.
5.2.3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
5.2.4. The test cassette should be discarded in a proper biohazard container after testing.
5.2.5. The test cassette should not be reused.
5.3. KIT STORAGE AND STABILITY:
5.3.1. Store as packaged in the sealed pouch at 2-30°C. The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. DO NOT use beyond the expiration date.
5.4. External Quality Control material:
5.4.1. The Point of Care Laboratory uses the Alere hCG Control Kit for Alere hCG Rapid Tests as urine external controls. These controls are stored in the refrigerator (2-8°C). The control material is stable refrigerated for 90 days from the date of opening or until the package expiration date.
5.4.2. NOT PROVIDED:
5.4.2.1. Timer or watch that measures minutes and seconds.
5.4.2.2. Specimen collection containers

6. SPECIAL SAFETY PRECAUTIONS:

6.1. All specimens must be considered potentially infectious and must be handled using universal precautions. Wear gloves during the entire testing procedure.
6.2. Perform testing behind safety shield.
6.3. Do not eat, drink, or smoke in the area where the specimens and kits are handled.
6.4. Used Test Cassettes and Disposable Droppers must be disposed of in biohazard waste.

7. CALIBRATION/PROGRAMMING/MAINTENANCE: N/A

8. QUALITY CONTROL:

8.1. External Quality Control:
8.1.1. Positive and negative urine controls will be run with each new lot of reagent, new shipment of reagents or at least monthly.
8.1.1.1. Barcode each kit for scanning lot numbers.
8.1.2. Document the results of the external controls on the L:DRIVE and in QML. DO NOT USE a box of tests without valid external controls.
8.2. External Positive Control:
8.2.1. Process the control as you would a patient sample. A positive result is indicated by two distinct red lines. One line should be in the control region (C) and another line should be in the test region (T).
8.3. External Negative Control:
8.3.1. Process the control as you would a patient specimen. A negative result is indicated by one red line in the control region (C). No apparent red or pink line appears in the test region (T).
8.4. Internal Control Features
8.4.1. The Alere hCG Combo test contains built-in control features. The Internal Positive Procedural control is indicated by a red line in the Control Window. The internal negative procedural control is a clear background in the Read Result Window. Document this control for each patient sample in the glucometer when entering the patient result.

9. TEST PROCEDURE:

9.1. PROCEDURAL NOTES
9.1.1. DO NOT remove the cassette from the foil pouch until you are ready to perform the test.

9.1.2. Use a new disposable dropper for each sample to avoid cross-contamination.
9.1.3. Use only the disposable droppers that are included in the kit to perform this test.
9.2. Place the test cassette on a clean and level surface. Hold the pipette vertically and transfer 3 full drops of urine (approx. 100 µL) to the specimen well of the test cassette, and then start the timer.
9.3. Avoid trapping air bubbles in the specimen well.
9.4. Wait for the red line(s) to appear. Read the result at 3-4 minutes when testing a urine specimen. Do not interpret results after the appropriate read time. It is important that the background is clear before the result is read.
9.5. DO NOT reuse the test cassette.
9.6. .Note: Some positive results may appear sooner.
9.7. Record the test result and indicate if the internal control was valid on the Nova StatStrip or Nova StatSensor.
9.8. AMB site Bradenton and the Upper Arlington Clinical Lab does not have a Nova meter, record results on the log.

10. CALCULATIONS: N/A

11. REPORTING RESULTS:
11.1. Refer to master listing chart for reference intervals
11.2. Results are entered using either the Nova StatSensor or Nova StatStrip point of care device.
11.2.1. Log into the Nova point of care meter using employee ID
11.2.2. Select Manual Test Entry
11.2.3. Select hCG
11.2.4. Input the kit lot number by either scanning the box or manually entering number; then accept
11.2.5. Input patient's CSN by either scanning or manually entering number and accept
11.2.6. Select patient test result (either positive or negative) and accept
11.2.7. Select the internal control result (either present or absent) and accept.
11.2.7.1. Patient result should only be reported if internal QC results are acceptable. If internal QC results are not acceptable, reject result on the meter and rerun with new Test Cassette.
11.2.8. The next screen is to review the patient ID and test result. If result and ID are correct, press 'accept'.
11.2.9. Result will be processed and will populate in patient electronic medical record once the meter is downloaded.

12. INTERPRETATION OF RESULTS:
12.1. POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
12.2. NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).
12.3. INVALID: Control line fails to appear. 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 cassette. If the problem persists, discontinue using the test kit immediately and contact the Point of Care Department.

13. LIMITATION OF PROCEDURE:

13.1. 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.
13.2. 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.
13.3. 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.
13.4. This test reliably detects intact hCG up to 500,000 mIU/mL. It does not reliably detect hCG degradation products, including free-beta hCG and beta core fragments. Quantitative assays used to detect hCG may detect hCG degradation products and therefore may disagree with the results of this rapid test.
13.5. 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 serum or urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
13.6. 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.
13.7. 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.

14. REFERENCES:

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14.3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade “Serum human chorionic gonadotropin levels throughout normal pregnancy”, *Am. J. Obstet. Gynecol.* 1976; 126(6): 678-681
14.4. 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
14.5. 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
14.6. Dawood MY, BB Saxena, R Landesman “Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma”, *Obstet. Gynecol.* 1977; 50(2): 172-181
14.7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross “Ectopic production of human chorionic gonadotropin by neoplasms”, *Ann. Intern Med.* 1973; 78(1): 39-45

15. RELATED DOCUMENTS:

15.1. Refer to QPulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms