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Alere hCG Combo Test

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform urine human chorionic gonadotropin (hCG) testing with the Alere hCG Combo Cassette in the main laboratory and at the point of care (POC) and to provide quality control (QC) and troubleshooting instructions.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PRINCIPLE AND CLINICAL SIGNIFICANCE:

A. hCG is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in 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 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in urine 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.

B. The Alere hCG Combo test is a rapid chromatographic immunoassay for the qualitative detection of 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 urine to the specimen 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.

C. 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 and the test cassette is functioning properly.

D. The Alere hCG Combo test is a rapid test that qualitatively detects the presence of hCG at the sensitivity of 20 mIU/mL in urine. At the level of claimed sensitivity, the Alere hCG Combo test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH (follicle-stimulating hormone), hLH (luteinizing hormone), and hTSH (thyroid stimulating hormone) at high physiological levels.

III. SPECIMEN COLLECTION AND HANDLING:

Always follow established procedures for Standard Precautions/Hand Hygiene when collecting and handling specimens. Hands must be washed or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control policy before and after gloves are used. Gloves must be worn when performing patient testing and changed between patients.

A. Patient Preparation
    1. A first morning specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used for testing.

B. Patient Identification
    1. Patients must be identified at the bedside using two identifiers (Joint Commission).

C. Specimen Labeling
    1. If hCG testing is not performed at the bedside, the specimen must be labeled with the patient name and identification (ID) number (Joint Commission).

D. Specimen Types
    1. Urine is the only acceptable specimen type.

E. Specimen Collection, Handling, Processing, Storage, and Transportation
    1. Urine samples must be collected in a clean and dry container.
    2. If specimens are to be shipped to the main laboratory, they should be packaged in compliance with federal regulations covering the transportation of etiologic agents. Samples must be transported in a sealable biohazard bag. Ship the samples by the quickest means possible. If the samples are to be sent via courier, enclose the sample in a cooler with a cold pack.
    3. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing. For testing at the point of care, allow for the precipitate to settle before testing or send to the main lab for centrifugation to obtain a clear specimen.
        a. Note: Taylor, Trenton, and Wayne laboratories do not perform qualitative urine hCG testing. If visible particulate matter prevents testing at the POC, it is recommended to collect a serum sample to send to those laboratories for testing the Total Beta hCG Level.

4. Urine may be stored refrigerated at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed prior to testing.

F. Specimen Storage/Disposal After Testing Completion
    1. Main Laboratory: Store specimens with the other refrigerated urine samples, per site protocol.
    2. POC: POC specimens are not stored. Dispose of the urine in an approved toilet or sink. Patient information on the specimen cup must be obscured (cover with a plain label or blacken out with a marker) before disposing in a trash container.

G. Specimen Acceptability Criteria
    1. Specimens collected in clean urine containers, free from visible particulate matter that are tested immediately after collection, or tested within 48 hours when stored at 2-8°C, or maintained at -20°C for prolonged storage.

H. Specimen Rejection Criteria
    1. Specimens collected in containers containing urine preservatives.
    2. Unlabeled specimens that are not tested at the bedside.
    3. Specimens with visible particulate matter should not be tested at the point of care.
    4. Serum samples have not been validated for this test cartridge and should not be tested using this method.

IV. REAGENTS:

A. Alere hCG Combo Kit
    1. Availability: Each box contains 40 individually sealed test pouches containing a disposable pipette and one directional insert per kit. The test kit contains complete reagent components and materials to perform all testing.
        a. All laboratories order and store their own kits.
        b. Dearborn POC: Kits are ordered and stored by each testing area.
        c. Farmington Hills POC: Kits may be picked up in the Hematology Laboratory department.
        d. Grosse Pointe POC: Kits may be obtained in the main laboratory.
        e. Lenox POC: Kits may be obtained from the Grosse Pointe laboratory.
        f. Livonia: Kits may be obtained from the Farmington Hills laboratory.
        g. Royal Oak POC: Kits for POC use may be picked up in Inventory Control/ Kanban. Off-site locations may call 248-898-8012 to obtain testing supplies.
        h. Taylor POC: Kits are ordered by the testing areas then delivered to the laboratory for QC testing. The approved kits may be picked up in the main laboratory.

i. Trenton POC: Kits are ordered by the testing areas then delivered to the laboratory for QC testing. The approved kits may be picked up in the hospital storeroom.

j. Troy POC: Decentralized Testing staff delivers supplies to nursing units.

k. Wayne POC: Kits are ordered by the testing areas then delivered to the laboratory for QC testing. The approved kits may be picked up in the main laboratory.

2. Ingredients: Each test cassette contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coated on the membrane.
3. Handling: Store in the sealed pouches at 2-30°C. Do not freeze. Do not use beyond the expiration date. The test cassette must remain in the sealed pouch until use.
4. Expiration: The test cassette is stable until the expiration date printed on the sealed pouch.
5. Warnings/Precautions: For *in vitro* diagnostic use only. Discard used cassettes in a biohazard container.

B. Alere hCG Control Kit

1. Availability: Each kit contains two (2) 4-mL vials: one positive and one negative. Each laboratory area will order and store their own controls.
2. Ingredients: The hCG controls are prepared from human-based urine. The positive control has been spiked with known quantities of purified hCG.
3. Storage: Store refrigerated at 2-8°C or at room temperature (18-25°C). Do not freeze. Do not use beyond the expiration date.
4. Expiration:
    a. Refrigerated Storage: The unopened controls are stable until the printed expiration date. Once opened, the controls are stable when returned to refrigerated storage temperatures after use for 90 days from the date of opening or until the manufacturer expiration date, whichever is first.
    b. Room Temperature Storage: If stored at room temperature, the controls are stable for 31 days or until the expiration date, whichever comes first, regardless of the date opened.
5. Handling: Protect from exposure to direct sunlight. Discard if cloudiness develops.
6. Precautions: For *in vitro* diagnostic use only. Discard the bottles in a biohazard container. The controls contain sodium azide. To prevent the formation of explosive metal azides in plumbing, dispose of the discarded material by flushing or diluting with copious amounts of water.

V. EQUIPMENT AND SUPPLIES:

A. Specimen Collection Container

B. Timer

C. Gloves

D. Biohazard Receptacle

E. Disposable Pipettes (External QC Procedure Only)

F. Test Tubes (External QC Procedure Only)

VI. QUALITY CONTROL (QC):

A. Internal Controls: Each test cassette has a built-in control. A red line at the control region (C) is the internal procedural control. It confirms sufficient specimen volume, correct procedural technique, and that the device is functioning properly. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

B. External Controls: External controls are used to confirm that the test cassettes are working and that the assay procedure was followed correctly. External controls are assayed when new lots and/or shipments are received, monthly as a check on continued storage conditions, when each new operator is trained, and for troubleshooting.

C. QC Procedure

1. Allow controls to warm to room temperature (15-30°C) and verify that the controls are not expired.
2. Mix by gentle inversion or swirling prior to use. Do not shake.
3. Expel some of the control material into a test tube labeled with the control identification. Be careful to replace the cap on the correct control vial.
4. Remove the hCG test devices and droppers from the pouches and place on a flat, dry surface. Label the test devices (positive and negative).
5. Squeeze the bulb of the disposable dropper and insert the barrel into the appropriate labeled test tube. Release the bulb and draw up the sample without bubbles.
6. Dispense 3 drops of sample into the specimen well of the test device. Discard the dropper in a biohazard waste container.
7. Start a timer for 3 minutes.
8. Read the test. The negative control should only have the appearance of a line at the control region (C). The positive control should have lines at both the test region (T) and the control region (C).
9. Document the results on the Urine hCG New Lot Number Validation and Monthly QC form
    a. Do not use devices for patient testing if the control results are unacceptable. Refer to the QC Failure Procedure below.
10. Discard the test device in a biohazard container.
11. Label the kits with a sticker indicating that they passed quality control and are ready for use.

D. QC Failure Procedure

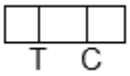
1. If unacceptable QC results appear, the following items should be verified:
    a. Verify that the QC and test cassettes are not past their expiration dates.
    b. Confirm proper temperature storage for QC and cassettes.
    c. Confirm that the proper procedure and technique were followed.
2. Repeat the test using new QC and cassette.

VII. PROCEDURE:

A. If stored in a refrigerator, allow the test cassette and/or urine specimen to equilibrate to room temperature (15-30°C) prior to testing.
B. Confirm that the test cassette is not past the expiration date.
C. Remove the test cassette from the sealed pouch and use it as soon as possible.
D. Label the test cassette with the patient ID and place the test cassette on a clean and level surface.
E. Hold the pipette vertically and transfer 3 full drops of urine (approximately 100 µL) to the specimen well of the test cassette then start the timer for 3 minutes. Avoid trapping air bubbles in the specimen well.
F. Read the result at 3-4 minutes. Do not interpret results after 4 minutes.
G. Dispose of the test device and dropper in a biohazard container or sharps biohazard container, pending availability.

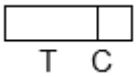
VIII. INTERPRETATION OF TEST RESULTS:

A. Positive: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).



    1. The intensity of the red color in the test region (T) will vary depending on the concentration of hCG present in the specimen. While the intensity of the test line may vary with different samples, the appearance of 2 distinct lines should be interpreted as a positive result, regardless of the intensity. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

B. Negative: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).



C. 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 cassette. If the problem persists, contact the site-specific POC Lab (see the troubleshooting section below for contact information). The laboratory may contact Alere Technical Support.

IX. RESULT REPORTING:

A. Laboratory

1. Results

a. Document the results on the Urine hCG Result Log, for applicable sites.

b. Report the results in the laboratory information system (LIS) using the Outstanding List.

2. QC

a. Document the results on the Urine hCG Lot to Lot form, for applicable sites.

b. Enter results into QC software such as Bio-Rad Unity.

B. POC (Dearborn, Taylor, Trenton, Wayne)

1. Results and QC

a. Open the patient's chart in Epic.

b. Navigate to the Enter/Edit Results tab.

c. Double click on the "POC Urine Pregnancy Test".

d. Enter the results for the test and internal QC in the window that appears.

C. POC (Farmington Hills, Grosse Pointe, Lenox, Livonia, Royal Oak, Troy)

1. Results and QC

a. All hCG results must be documented in the patient's electronic health record via Manual Test Entry (MTE) or WebMRE. After verifying that both internal procedural controls are valid (control line (C) is present and the background of the test window is clear), document the test result and internal quality control results in MTE or WebMRE.

i. MTE (Manual Test Entry in the Nova StatStrip Meter)

a. Press "Login/OK" on the Nova meter.

b. Enter Operator ID: Scan the bar code on the employee ID badge.

c. Choose "Manual".

d. Choose "Manual Patient" then "Accept/OK".

e. Choose "Urine Preg".

f. The blue display bar will read "Enter Manual Lot". Press "List". Lot ID numbers and expiration dates will be displayed. Choose the appropriate lot then press

"Accept/OK".

i. If the lot number used for testing is not listed, enter the lot number manually.

g. The blue display bar will read "Enter Patient ID". Enter the patient ID by scanning the wristband bar code or typing in the patient's contact serial number (CSN) and press "Accept/OK".

i. If the "……is not a valid Patient ID" message appears, verify that the ID is correct and proceed by choosing "Downtime Override".

h. The blue display bar will read "C Line OK". Choose "Yes" or "No" to document the presence or absence of the internal control line and "Accept/OK".

i. The blue display bar will read "Clear Bkg". Choose "Yes" or "No" to document the presence or absence of a clear background and "Accept/OK".

j. The blue display bar will read "Pat Test". Choose either "Positive" or "Negative" to document the test result and "Accept/OK".

k. The result appears for final verification. Press "Comment" to free text a comment, if needed. Press "Accept/OK" or "Reject" to finalize the result.

i. Note: If "No" has been selected for either steps h or i, the patient test results will not download into the electronic health record. The test is invalid and should be repeated.

l. Return the meter to the docking station when not in use.

ii. WebMRE

a. Log on to WebMRE and complete the following fields:

i. Patient ID: enter the patient's CSN and press "Enter".

i. A pop-up will appear with the patient location, medical record number (MRN), Account (CSN), name, sex, and date of birth (DOB).

ii. Click "Select" to choose the patient.

iii. Upon selecting the patient, WebMRE will return to the

resulting screen and populate the patient's name. Confirm the name and ID are correct.

ii. Collection Date and Time: the default is set to the current date and time. Change if appropriate.

iii. Performed by: the default is set to the operator logged into WebMRE.

iv. Click the "+" sign next to "Pregnancy" plus the testing site to expand the branch.

v. Lot in Use and Lot Expiration Date: click on the notepad icon and select the appropriate lot number from the drop down list. This will automatically populate the expiration date of the kit.

vi. Device Code: select the appropriate testing location from the drop down list.

vii. Performed Date and Performed Time: the default is set to the current date and time. Change if appropriate.

viii. Test: select the result from the "POC Preg" drop down list.

ix. The Control Line defaults to "Present" and the Clear Background defaults to "Present". If applicable, change Control line to "Absent" and/or Clear Background to "Not Present". If "Absent" and/or "Not Present" are selected, results will not download into the patient's electronic health record. The test is invalid and should be repeated.

x. Click on the disk icon to save the results. A system message will appear asking the operator to verify entry of patient results for the collection date and time specified. Click "OK" to continue.

Note: For POC users in surgical and pre-op/pre-procedure areas, the physician must be notified of a positive hCG result. A blood specimen may be sent to the main laboratory, if desired.

X. EXPECTED VALUES:

A. Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine specimens. The amount of hCG will vary greatly with gestational age and between individuals.

1. Elevated hCG concentrations in urine, unrelated to pregnancy, may occur in patients with choriocarcinoma, hydatidiform mole and some nontrophoblastic malignancies including testicular, prostatic, breast, and lung carcinomas.

B. The Alere hCG Combo test has a sensitivity of 20 mIU/mL in urine and is capable of detecting pregnancy as early as 1 day after the first missed menses.
    1. The qualitative urine hCG assay (sensitivity 20 mIU/mL) is expected to be positive and can diagnose 100% of pregnant patients by days 24-32.
    2. A single negative pregnancy test cannot absolutely rule out pregnancy. After ovulation and conception, the embryo moves throughout the fallopian tube and implants into the endometrium. Ovulation usually, but not always, occurs at the end of the second week (day 14) of the menstrual cycle and implantation occurs approximately one week later (day 21). hCG is not detected in maternal blood until after implantation. Therefore, a negative hCG result may be obtained in the earliest stages of pregnancy.
    3. Laboratory-based serum quantitative hCG is the preferred immunochemical test to aid in the detection of pregnancy and other conditions that result in hCG elevations.

XI. REPORTABLE RANGE:

Negative or Positive

XII. CRITICAL VALUES:

A. None

B. For POC users in surgical and pre-op/pre-procedure areas, the physician must be notified of a positive hCG result. A blood specimen may be sent to the main laboratory, if desired.

XIII. SYSTEM DOWNTIME:

If laboratory or hospital information system is down, follow department's downtime procedure and verify that all notes are documented on the Urine hCG Result Log for later result entering/scanning when the system becomes available. Verify that date/time of test, result and QC outcome are documented. Results will be entered when the system is available.

XIV. LIMITATIONS AND INTERFERING SUBSTANCES:

A. 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.

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 urine specimen should be collected 48 hours later and tested.

C. Very low levels of hCG (less than 50 mIU/mL) are present in urine 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 urine specimen collected 48 hours later.

D. 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.

E. 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 urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.

F. 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 (human anti-mouse antibody). Such specimens may cause false positive or false negative results.

G. 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.

H. Urine specimens with visible precipitates must be sent to the main laboratory for testing or a blood specimen may be drawn and sent to the main laboratory for testing.

I. Use only the transfer pipettes contained in the test kit. Do not reuse pipettes. The use of non-class A measuring devices for testing has been approved by the manufacturer.

XV. TROUBLESHOOTING:

A. Testing personnel will initiate basic corrective action when results are questionable or if the internal controls do not react as expected. Patient results are invalid if the QC fails and must not be reported. If problem remains unsolved, refer to this troubleshooting guide for additional corrective action recommendations, contact the site-specific Point of Care department, and send a specimen to the laboratory for analysis, if needed.

B. Corrective Action Recommendations:

1. Verify expiration dates on the pouch. Do not use if product is past expiration date.
2. Verify proper storage conditions.
3. Verify proper procedure was followed to perform testing.

C. If the problem cannot be resolved using the recommendations above, contact the appropriate main laboratory supervisory staff or the site-specific POC department below.

1. Dearborn POC: Call POC at 313-436-2367, 313-593-7970, or 313-982-5661.
2. Farmington Hills POC: Call the POC/Quality Lead MT at 947-521-7167.
3. Grosse Pointe POC: Call POC at 313-473-1831.
4. Lenox: Call POC at 313-473-1831.

5. Livonia: Call the POC/Quality Lead MT at 947-521-7167.
6. Royal Oak POC: Call Ancillary Testing at 248-898-8012.
7. Taylor POC: Call the Taylor Lab Manager at 313-295-5369.
8. Trenton POC: Call the Trenton Lab Manager at 734-671-3859.
9. Troy POC: Call Decentralized Testing at 248-964-8009.
10. Wayne POC: Call the Wayne Lab Manager at 734-467-4233.

XVI. REFERENCES:

A. Point of Care Testing Approval Process
B. Alere hCG Combo Cassette (20/10 mIU/mL) (40 Tests) CLSI + More Packet Laboratory Procedure, Alere, San Diego, CA 92121, revision CLSI180 vC 08/2016 https://www.globalpointofcare.abbott/en/product-details/hcg-combo-ii.html
C. Alere Qualitative hCG Primer, Alere, San Diego, CA 92121, revision 7000185-04 06/19 https://www.globalpointofcare.abbott/en/product-details/hcg-combo-ii.html
D. Alere hCG Control Kit for Alere hCG Rapid Tests Package Insert, Alere, San Diego, CA 92121, revision 7000472 v1 07/2014 https://www.globalpointofcare.abbott/en/product-details/hcg-combo-ii.html
E. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.

Attachments

POC Urine hCG Training and Competency Assessment Form.pdf

Urine hCG New Lot Number Validation Form and Monthly QC.pdf

Urine hCG Result Log.pdf

Urine hCG Training Guide.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	7/18/2023
CLIA Medical Directors	Muhammad Arshad: Chief, Pathology	7/4/2023

CLIA Medical Directors	Jeremy Powers: Chief, Pathology	6/29/2023
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	6/28/2023
CLIA Medical Directors	John Pui: Chief, Pathology	6/28/2023
Policy and Forms Steering Committee (if needed)	Jessica Czinder: Mgr, Division Laboratory	6/28/2023
	Ann Marie Blenc: System Med Dir, Hematopath	6/27/2023
	Caitlin Schein: Staff Physician	6/22/2023
	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	6/12/2023
Best Practice Committee - Hematology	Megan Masakowski: Mgr, Division Laboratory [BB]	6/9/2023
Best Practice Committee - Chemistry	Colette Kessler: Mgr, Division Laboratory	5/31/2023
Best Practice Committee - Point of Care	Jessica Czinder: Mgr, Division Laboratory	5/31/2023
	Jessica Czinder: Mgr, Division Laboratory	5/31/2023

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne