# SCOPE:

This document applies to UPMC Hanover Laboratory.

# PURPOSE:

The Alere™ hCG Combo (20/10 mlU/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 is utilized as a near-patient (point of care) test.

**PRINCIPLE:**

1. The Alere hCG 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. For professional *in vitro* diagnostic use only.
2. Human chorionic gonadotropin (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 100mIU/mL by the first missed menstrual period, and peaking in the 100,000-200,000mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both 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
3. The Alere hCG test is a rapid test that qualitatively detects the presence of hCG at the sensitivity 10 mIU/mL in serum and 20 mlU/mL in urine. 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, the Alere hCG test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

**REAGENTS:**

The Alere hCG Combo Cassette Serum/Urine hCG-STAT test kit.

**Materials Supplied**

* Reaction cassette
* Disposable dropper

**Materials Required but not Provided**

* Timer or watch that measures minutes or seconds
* Specimen collection containers
* QC Material [Serum: BioRad Immunoassay 1 (negative) and 3 (positive)]

[Urine: Quantimetrix Dropper Plus 1 (negative) and 2 (positive)]

**Storage and Stability**

* Store as packaged in the sealed pouch at 2-30°C (35-86°F).  Do not Freeze.
* The testing device must remain in the sealed pouch until use.
* The test device is stable until the expiration date printed on the sealed pouch.
* Do not use beyond expiration date.

**WARNING AND PRECAUTIONS:**

* For *in vitro* diagnostic use
* Do not use contents of kit after expiration date printed on the outside of the box.
* The Reaction unit must remain sealed in the foil pouch just prior to use.
* To obtain accurate results, package insert instructions must be followed.

**SPECIMEN COLLECTION AND STORAGE:**

**Urine**

* Collect urine in a clean container. First morning specimens are optimal, because it contains the greatest concentration of hCG.
* Samples can be stored 8 hours at 15-30°C or up to 72 hours at 2-8°C.
* Do not freeze urine sample.
* EPIC order test code is **Pregnancy, Urine [LAB437]**.

**Serum**

* No special patient preparation is necessary. Obtain whole blood, allow to clot and use the separated serum for testing.
* Use clear non-hemolyzed specimens when possible.
* Serum specimens may be stored at 2-8°C. for up to 48 hours.
* If testing is delayed for more than 48 hours, the sample may be frozen once at -20°C. If frozen, mix after thawing. Do not refreeze.
* EPIC order test code is **Pregnancy,Qualitative [LAB4033 or LAB4034]**.

**QUALITY CONTROL:**

**External Quality Control**

* Run positive and negative controls for urine and serum HCG with each new shipment and once every 30 days.
* Process controls as for patient samples. See procedure below.
* Refer to the test Risk Assessment as documented in the IQCP for additional information.

**Internal Control Features**

* A red line in the Control Region (C) is an internal positive procedural control.
* A clear background in the Read Result Window is considered an internal negative procedural control.
* If internal controls do not perform as expected, repeat with a new test device. If still invalid, **do not** report patient results. Contact technical support, if indicated. If a result is still needed recommend a quantitative hCG test to the doctor.

**TEST PROCEDURE:**

|  |  |
| --- | --- |
| Step | Action |
| 1 | Remove the Reaction cassette from the foil pouch. Allow to warm to RT (15-30°C) prior to testing if refrigerated. |
| 2 | Draw serum or urine into the disposable dropper. Hold the dropper vertically and dispense **3 drops** into the **Add Sample** well. Avoid trapping air bubbles in the specimen well.  A test tube with drops of water  Description automatically generated  **NOTE:** After the sample is added, a pink to purple color will be seen moving across the Reaction Unit’s windows. The **Read Result Window** contains a preprinted horizontal blue line on the membrane |
| 3 | **Read result at 3-4 minutes for urine and 5-6 minutes for serum.**  **Note:** Some positive results may appear sooner. |

**INTERPRETATION OF RESULTS**

**Positive Result:**

Positive results are indicated by **two distinct red lines.** One line should be in the Control region [C] and the other in the Test region [T].

A diagram of a positive test

Description automatically generated with medium confidence

**Negative Results:**

One red line appears in the Control region [C]. No apparent red or pink line appears in the Test region [T].

A black and white symbol with text

Description automatically generated

**Invalid Result:**

No red line in the Control Window.

Background color in the Read Result Window interferes with test interpretation.

A black and white diagram of a pill

Description automatically generated with medium confidence

**Notes**:

* In case of an invalid result, a repeat the testing with a fresh cartridge. If still invalid, a fresh specimen should be tested or contact Technical Support at the phone number noted in the Package Insert.
* If a negative result is obtained, but pregnancy is suspected, another sample should be collected after 48-72 hours and tested.

**REPORTING OF RESULTS IN EPIC:**

* Manually record external control results on the “HCG Quality Control Log.”
* The internal control will be recorded with each patient result. When entering the patient result in EPIC, enter “S”- Satisfactory or “U” – Unsatisfactory in the space provided. Use the “Test Comment” function to append the test kit lot number to the Internal Control result.
* All negative urine results will automatically include the interpretive statement “False negative results may occur with dilute urine samples. If pregnancy is still suspected, a first-morning sample should be obtained and tested”.
* **POSITIVE** SERUM OR URINE HCG QUALITATIVE RESULTS ON SAME DAY SURGERY OR OPERATING ROOM PATIENTS WILL BE CALLED TO THE APPROPRIATE UNIT STAT. Document the name of the individual notified and the time called in Specimen Comments.

**LIMITATIONS:**

* 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.
* A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG values alone.
* 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.
* Very low levels of hCG are present in serum and urine shortly after implantation. Positive test results from a very early pregnancy may later be negative due to natural termination of pregnancy. This is estimated to occur in 50% of conceptions. If a very low, faint positive serum results is obtained, another sample should be obtained in 48 hours and retested. If waiting 48 hours is not medically advisable, the test result should be confirmed with a quantitative hCG test.
* Patients with trophoblastic and nontrophoblastic disease may have elevated hCG levels, therefore, the possibility of hCG secreting neoplasms should be eliminated prior to diagnosis of pregnancy.
* If a urine sample is too dilute, it may not contain a representative hCG concentration.
* 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 ay conatin HAMA. Such specimens may cause false positive or false negative results.

**EXPECTED VALUES:**

* The sensitivity of the Alere hCG Combo Cassette test is 10 mlU/ml for serum or 20 mlU/ml for urine.
* In normal pregnancy, hCG levels in urine can reach 25 mlU/ml as early as 7 to 10 days post conception, and continue to increase exponentially to reach a maximum concentration in excess of 200,000 mlU/ml at the end of the first trimester.

**REFERENCES:**

Alere hCG Combo Cassette (20/10 mIU/mL) package insert 07/16

Alere hCG Combo Cassett (20/10mIU/mL) Risk Assessment / Individualized Quality Control Plan (IQCP), UPMC Hanover

**Document History**

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| Date of Origination and Document Control Number | December 15, 2024 | Method implementation.  Replaces CHEM 6001.1 and CHEM 6003.3 |
| Prepared by: Marilee Klunk, MT(ASCP) |
| Revision History/ Biennial Review: |  |  |
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