Overview

Useful For
Early detection of pregnancy
Investigation of suspected ectopic pregnancy or other pregnancy-related complications
Monitoring in vitro fertilization patients
This test is not useful for detecting or monitoring tumors or gestational trophoblastic disease (GTD).

Method Name
Electrochemiluminescent Immunoassay

NY State Available
Yes

Specimen

Specimen Type
Serum

Ordering Guidance
For use as a tumor marker (eg, testicular cancer patients), see BHCG / Beta-Human Chorionic Gonadotropin, Quantitative, Serum.

Specimen Required
Patient Preparation: For 12 hours before specimen collection do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Container/Tube:
Preferred: Serum gel
Acceptable: Red top

Specimen Volume: 0.5 mL

Collection Instructions:
1. Serum gel tubes should be centrifuged within 2 hours of collection.
2. Red-top tubes should be centrifuged and the serum aliquoted into a plastic vial within 2 hours of collection.

Reject Due To
Gross hemolysis  Reject
Gross lipemia  OK
Gross icterus  Reject

Specimen Minimum Volume
0.4 mL

Specimen Stability Information
Human chorionic gonadotropin (hCG) is a glycoprotein hormone that consists of 2 subunits (alpha and beta chains) that are associated to comprise the intact hormone. The alpha subunit is similar to those of luteinizing hormone, follicle-stimulating hormone, and thyrotropin (previously known as thyroid-stimulating hormone). The beta subunit of hCG differs from other pituitary glycoprotein hormones, which results in its unique biochemical and immunological properties. This method quantitates the sum of intact hCG plus the beta subunit.

hCG is produced in the placenta during pregnancy. In nonpregnant individuals, it can also be produced by tumors of the trophoblast, germ cell tumors with trophoblastic components, and some non-trophoblastic tumors. The biological action of hCG serves to maintain the corpus luteum during pregnancy. It also influences steroid production. The serum in pregnant individuals contains mainly intact hCG. Measurement of the hCG concentration permits the diagnosis of pregnancy as early as 1 week after conception.

Reference Values
Negative: <5 IU/L

Interpretation
Values in pregnancy should double every 2 to 3 days for the first 6 weeks.
Elevated concentrations of human chorionic gonadotropin (hCG) measured in the first trimester of pregnancy are observed in normal pregnancy but may serve as an indication of choriocarcinoma, hydatiform mole, or multiple pregnancy.

Decreasing hCG concentrations indicate threatened or missed abortion, recent termination of pregnancy, ectopic pregnancy, gestosis, or intrauterine death.

Both normal and ectopic pregnancies generally yield positive results of pregnancy tests. The comparison of quantitative hCG measurements with the results of transvaginal ultrasonography (TVUS) may aid in the diagnosis of ectopic pregnancy. When an embryo is first large enough for the gestation sac to be visible on TVUS, the patient generally will have hCG concentrations between 1000 and 2000 IU/L. (These are literature values. Definitive values for this method have not been established at this time.) If the hCG value is this high and no sac is visible in the uterus, ectopic pregnancy is suggested. Elevated values will also be seen with choriocarcinoma and hydatiform mole.

Peri- and postmenopausal females may have detectable hCG concentrations (< or = to 14 IU/L) due to pituitary production of hCG. Serum follicle-stimulating hormone measurement may aid in ruling-out pregnancy in this population. Cutoffs of greater than 20 to 45 IU/L have been suggested and are method dependent.

Cautions
False-elevations (called phantom human chorionic gonadotropin: hCG) may occur with patients who have human anti-animal or heterophilic antibodies.
Some specimens may not dilute linearly due to abnormal forms of hCG.
Elevated hCG concentrations not associated with pregnancy are found in patients with other diseases such as tumors of
the germ cells, ovaries, bladder, pancreas, stomach, lungs, and liver. However, this test is not intended for the detection of or to monitor for tumors or gestational trophoblastic disease.

**Clinical Reference**

**Performance**

**Method Description**
This method employs 2 monoclonal antibodies specifically directed against human chorionic gonadotropin (hCG). A biotinylated monoclonal antibody and a second monoclonal antibody labeled with a ruthenium complex react with hCG to form a sandwich complex. After the addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Application of a voltage to the electrode then induces chemiluminescent emission, which is measured by a photo multiplier. (Package insert: HCG+B. Roche Diagnostics; 11/2018)

**PDF Report**
No

**Specimen Retention Time**
7 days

**Performing Laboratory Location**
Rochester

**Fees & Codes**

**Test Classification**
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**
84702

**LOINC® Information**

<p>| Test ID | Test Order Name | Order LOINC Value |</p>
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**Test Definition: THCG**

HCG, Quantitative, Pregnancy, S