Lab Dept: Chemistry

Test Name: HCG, BETA-SUBUNIT, SERUM

General Information

Lab Order Codes:	BHCG
Synonyms:	Chorionic Gonadotropin, Beta-Subunit (Quantitative), serum; Beta HCG Tumor Marker
CPT Codes:	84702 – Gonadotropin, chorionic; quantitative
Test Includes:	HCG, Beta subunit level reported in IU/L.

Logistics

Test Indications:	Useful for monitoring patients for retained products of conception. Diagnosis of gestational trophoblastic disease (GTD), testicular tumors, ovarian germ cell tumors, teratomas, and, rarely, other human chorionic gonadotroping (hCG)-secreting tumors. Serial measurement of hCG following treatment to: ● Monitor therapeutic response to GTD or in hCG-secreting tumors ● Detect persistent or recurrent GTD or hCG-secreting tumors It is not meant to be used for pregnancy testing.
Lab Testing Sections:	Chemistry – Sendouts
Referred to:	Mayo Medical Laboratories (MML Test: BHCG)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1 - 3 days, test set up Monday - Saturday
Special Instructions:	This test is not meant to be used for pregnancy testing.

Specimen

Specimen Type:	Blood
Container:	SST (Gold, marble or red) tube

Draw Volume:	1.8 mL (Minimum: 1.5 mL) blood
Processed Volume:	0.6 mL (Minimum: 0.5 mL) serum
Collection:	Routine venipuncture
Special Processing:	Lab Staff: Centrifuge specimen, remove serum aliquot into a screw-capped round bottom plastic vial. Store and ship at refrigerated temperatures. Forward promptly.
Patient Preparation:	None
Sample Rejection:	Specimens other than serum; gross hemolysis; warm specimens; mislabeled or unlabeled specimens

Interpretive

Reference Range:

Children:	
Birth – 3 months:	Males & Females: ≤50.0 IU/L*
>3months - <18 years:	Males: <1.4 IU/L Females: <1.0 IU/L
*hCG, produced in the placenta partially passes the placental barrier. Newborn serum beta hCG concentrations are approximately 1/400th of the corresponding maternal serum concentration, resulting in neonate beta hCG levels of 10-50 IU/L at birth. Clearance half-life is approximately 2-3 days. Therefore, by 3 months of age, levels comparable to adults should be reached.	
Adults (97.5 percentile):	
Males: <1.4 IU/L	
Females:	
Premenopausal, non -pregnant:	<1.0 IU/L
Postmenopausal:	<7.0 IU/L

Critical Values: N/A

Limitations: The purpose of this assay is for following the course of therapy of tumors, such as such as choriocarcinoma. It is not meant for pregnancy testing.

Despite strenuous efforts at standardization, different hCG assays show

only modest agreements with each other. Therefore, whenever serial monitoring of hCG concentrations is required, the same assay should be used for all measurements.

Transient elevations of serum hCG can occur following chemotherapy in patients with susceptible tumors, due to massive tumor cell lysis; these transient elevations should not be confused with tumor progression.

Normal serum levels of hCG do not always exclude tumor persistence since tumors may undergo transition to differentiated teratomas, which may not produce hCG.

In individuals with incomplete or complete primary hypogonadism (eg, menopausal women, XXY males, surgically or medically castrated individuals who are receiving inadequate sex steroid replacement therapy), increases LH-gene transcription results in minor “leaky” transcription of hCG and hCG levels of 3-5 IU/L may be seen, in some cases levels as high as 25 IU/L may be seen. In post-menopausal women hCG levels ranging from 3.5 IU/L to 32 IU/L have been reported. In these cases, measurements of serum concentrations of sex hormones might be indicated.

End-stage renal failure is associated with up to 10-fold elevations in serum hCG levels.

Among immunometric assays, hCG assays have been found uniquely susceptible to heterophile antibody interference, resulting in occasional false-positive results. Our current assay has been proven robust in this respect, but rare interferences still occur. Typically, the observed false-positive elevations are modest, ranging from just above the reference range to levels of 50-60 IU/L. If such results are seen and are discordant with the clinical picture or other biochemical or imaging tests, then the laboratory should be alerted. Rerunning the specimen in question after additional blocking treatment may resolve the issue. For patients with apparent serum hCG concentrations >15-20 IU/L, hCG should also be detectable in urine, if it is truly elevated. Failure to detect urinary hCG in such patients, supports a false-positive serum hCG test.

In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. The laboratory should be alerted if hCG value does not correlate with clinical presentation.

In patients receiving therapy with high biotin doses (ie, >5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration.

Methodology: Electrochemiluminescence Immunoassay

References: Mayo Medical Laboratories Web Page (November 2017)

Updates:	6/6/2011: Updated reference ranges, draw volume and serum volume change – previously 3 mL draw and 1 mL serum. 10/4/2012: Updated method and reference ranges. Method previously listed as Immunoenzymatic Assay. CPT change, previously listed as 84704.