Lab Dept: Chemistry

Test Name: CHORIONIC GONADOTROPIN BETA , SERUM

General Information

Lab Order Codes:	BHCG
Synonyms:	Beta-hCG; Beta Human Chorionic Gonadotropin; CG (Chorionic Gonadotropin); hCG Tumor Marker
CPT Codes:	84702 – Gonadotropin, chorionic, quantitative
Test Includes:	Chorionic gonadotropin, beta subunit levels measured in IU/L.

Logistics

Test Indications:	Useful for evaluation of patients with gestational trophoblastic disease, testicular tumors, and ovarian germ cell tumors. Serial measurement of hCG following treatment is indicated to identify persistent gestational trophoblastic disease, rule out metastatic disease, detect persistent or recurrent testicular or ovarian tumors, monitor the response to therapy in patients with testicular tumors.
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 performed Monday - Saturday
Special Instructions:	The purpose of this assay is for following the course of therapy of tumors, such as choriocarcinoma. It is not meant to be used for pregnancy testing.

Specimen

Specimen Type:	Blood
Container:	SST (Gold, marble or red)
Draw Volume:	1.8 mL (Minimum: 1.5 mL) blood

Processed Volume: 0.6 mL (Minimum: 0.5 mL) serum

Collection: Routine blood collection

Special Processing: Lab Staff: Centrifuge specimen, remove serum aliquot into a screw-capped round bottom plastic vial. Store and ship specimen at refrigerated temperatures. Forward promptly.

Patient Preparation: None

Sample Rejection: Specimens other than serum; mislabeled specimens; gross hemolysis

Interpretive

Reference Range:

Gender/Age:	**Range (IU/L)**
Term Infants, ≥36 weeks gestation - ≤3 months (Male and Female):	≤50.0 IU/L
>3 months – ≤18 years:	Males: <1.4 IU/L Females: <1.0 IU/L
HCG, produced in the placenta partially passes the placental barrier – fetal serum hCG concentrations new term are approximately 1/400th of the corresponding maternal serum concentrations, resulting in fetal hCG levels of 10 – 50 IU/L at birth. Clearance half-life is approximately 2-3 days. Therefore, by age 3 months of age, levels comparable to adults should be reached.	
Adult Males:	<1.4 IU/L
Adult Females:	
Premenopausal:	<1.0 IU/L
Postmenopausal:	<3.3 IU/L

Critical Values: N/A

Limitations:

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 (e.g. menopausal women, XXY males, surgically or medically castrated individuals who are receiving inadequate sex steroid replacement therapy), increased luteinizing hormone (LH)-gene transcription results in minor "leaky" transcription of hCG and hCG levels of 3-5 IU/L and, in some cases, levels as high as 25 IU/L, may be seen. In postmenopausal women, hCG levels ranging from 3.5 to 32 IU/L have been reported. In these cases, measurements of serum concentrations of sex hormones (LH and follicle-stimulating hormone) 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 sample 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 values do not correlate with the 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 January 2018

Updates:

11/15/2005: Addition of pediatric reference ranges. Method update.
5/6/2008: CPT update previously listed as 84702.
12/3/2012: CPT update, previously listed as 84704.
1/18/2018: Collection container and method update