



MAYO
Mayo Medical Laboratories
1-800-533-1710

NEW TEST ANNOUNCEMENT

MML JACKSONVILLE

NOTIFICATION DATE: December 18, 2012

EFFECTIVE DATE: January 22, 2013

BETA-HUMAN CHORIONIC GONADOTROPIN, QUANTITATIVE, SERUM

Test ID: 800087

USEFUL FOR:

- Monitoring patients for retained products of conception
- Aid in the diagnosis of gestational trophoblastic disease (GTD), testicular tumors, ovarian germ cell tumors, teratomas, and, rarely, other human chorionic gonadotropin (hCG)-secreting tumors
- Serial measurement of hCG following treatment to:
 - Monitor therapeutic response in GTD or in hCG-secreting tumors
 - Detect persistent or recurrent GTD or hCG-secreting tumors

METHODOLOGY: Roche Cobas Electrochemiluminescence Immunoassay

REFERENCE VALUES:

Children

Males

Birth-3 months: < or =50 IU/L*

>3 months-< 18 years: <1.4 IU/L

Females

Birth-3 months: < or =50 IU/L*

>3 months-< 18 years: <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 concentrations, 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 (97.5th percentile)

Males: <1.4 IU/L

Females

Premenopausal, nonpregnant: <1.0 IU/L

Postmenopausal: <7.0 IU/L

SPECIMEN REQUIREMENTS: Collection Container/Tube: Red Top
Acceptable Collection Container/Tube: Serum gel
Specimen Volume: 2 mL

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Serum	Refrigerated (preferred)	7 days
Serum	Frozen	7 days

CAUTIONS:

- The purpose to this assay is for following the course of therapy of tumors, such as choriocarcinoma. It is not meant to be used for pregnancy testing.
- Despite strenuous efforts at standardization, different human chorionic gonadotropin (hCG) assays show only modest agreements with each other. Therefore, whenever serial monitoring of hCG concentration 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), increased luteinizing hormone (LH)-gene transcription results in minor "leaky" transcription of hCG, and hCG levels of 3 to 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 to 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 to 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 does 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.

CPT CODE: 84702**DAY(S) SET UP:** Monday through Saturday **ANALYTIC TIME:** 1 day

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Greg Renkly, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710