MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: August 25, 2020
Effective Date: September 3, 2020

Interference Evaluation Heterophile, Beta-Human Chorionic Gonadotropin, Serum

Test ID: IEHCG

Useful for:

Evaluation of suspected interference from heterophile antibodies causing a falsely elevated human chorionic gonadotropin (hCG) result

This test is **not to be used** for pregnancy testing.

Profile Information:

Test ID	Reporting Name	Available Separately	Always Performed
HCGII	HCG, Interference Interpretation	No	Yes
HCGQN	Beta-HCG, Quantitative, S	Yes (order BHCG)	Yes
HCGAM	HCG, Alternative Method, S	No	Yes

Testing Algorithm:

Heterophile antibody evaluation consists of pretreatment with commercial heterophile antibody blocking reagents, testing on an alternate platform, and serial dilution of the sample.

Methods:

HCGQN: Electrochemiluminescent Immunoassay
HCGAM: Immunoenzymatic Assay

Reference Values:

BETA-HUMAN CHORIONIC GONADOTROPIN, QUANTITATIVE, SERUM
Children(1,2)
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
Pediatric reference values based on:

1. Chen RJ, Huang SC, Chow SN, Hsieh CY: Human chorionic gonadotropin pattern in maternal circulation. Amniotic fluid and fetal circulation in late pregnancy. J Reprod Med. 1993;38:151-154
2. Schneider DT, Calaminus G, Gobel U: Diagnostic value of alpha 1-fetoprotein and beta-human chorionic gonadotropin in infancy and childhood. Pediatr Hematol Oncol. 2001;18:11-26
*Human chorionic gonadotropin (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

HUMAN CHORIONIC GONADOTROPIN, ALTERNATIVE METHOD
Males
Birth-3 months: Not established
>3 months-49 years: <0.6 IU/L
50 years-80 years: <1.6 IU/L
>80 years: Not established

Females
Birth-3 months: Not established
>3 months-40 years: <0.6 IU/L
41 years-50 years: <6.2 IU/L
51 years-150 years: <7.8 IU/L

Specimen Requirements:

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.

Supplies: Aliquot Tube, 5 mL (T465)

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 2.5 mL

Minimum Volume: 1.5 mL

Specimen Stability Information:

Specimen Type	Temperature	Time
Serum	Refrigerated (preferred)	7 days
	Ambient	24 hours
	Frozen	365 days

Cautions:
Values obtained with different assay methods or kits may be different and cannot be used interchangeably.

Test results cannot be interpreted as absolute evidence for the presence or absence of malignant disease.

This heterophile antibody interference evaluation does not rule out the presence of other types interfering substances such as biotin.

There may be some samples with extremely strong heterophilic interference. In such cases heterophile blocking reagents may not be able to block all of the assay interference.
Despite strenuous efforts at standardization, different human chorionic gonadotropin (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), 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 measurement 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.

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.

CPT Code:
84702 x 2

Day(s) and Time(s) Performed:
Monday through Friday; 8 a.m.-10 p.m.
Saturday; 8 a.m.-5 p.m.

Analytic Time:
1 day

Questions
Contact Kim Terrio, Laboratory Technologist Resource Coordinator at 800-533-1710.