
LAB ALERT – NEW TEST**NOTIFICATION DATE: 1/31/2014****EFFECTIVE DATE: 2/4/2014****UPDATED CPT CODES: TESTOSTERONE, MALES FREE AND TOTAL WITH SHBG AND ALBUMIN****NEW TEST CODE:** TESSHB**INTERFACE CODE:** 1004499**OLD TEST CODES TO
BE DEACTIVATED:** FTEST/1002079
TSTFTM/1003360**METHODOLOGY:** Chemiluminescent microparticle immunoassay (CMIA),
Immunoassay and Spectrophotometry (Testosterone and SHBG) &
Spectrophotometry (Albumin)**CLINICAL UTILITY:** **Testosterone:**

Testosterone in blood exists in two forms i.e. predominantly protein (sex hormone binding globulin [SHBG] and albumin) bound and a small proportion of free. The free testosterone is considered to be functionally active. The testosterone binds to albumin with a relative low affinity compared to SHBG and is therefore, considered bioavailable.

Testosterone measurements are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males.

The Free Testosterone value reported in this method is a "Calculated" value derived mathematically based upon the binding constants of Testosterone for SHBG and Albumin. Free testosterone measurement is useful in evaluation of suspected hypogonadism in men with a total testosterone level at the lower limit of the reference range. This test is not recommended for use in women and children.

Note:

If the testosterone results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

Do not use samples from patients receiving the following compounds as they interfere in this assay:

D-(-)Norgestrel (1000 ng/mL)
19-nortestosterone (Nandrolone)
Ethinisterone
11b-Hydroxytestosterone
11-Ketotestosterone

SHBG:

Plasma SHBG concentrations are affected by a number of different diseases. Elevated levels are observed in patients with hyperthyroidism, hypogonadism, androgen insensitivity and hepatic cirrhosis in men. Low levels are observed in patients with myxoedema, hyperprolactinaemia and syndromes of excessive androgen activity. Measurement of SHBG is useful in the evaluation of mild disorders of androgen metabolism and also enables identification of those women with hirsutism who are more likely to respond to estrogen therapy.

Note:

For diagnostic purposes, the SHBG assay results should be used in conjunction with other data; e.g. symptoms, results of other tests and clinical impressions etc. and if required additional testing should be performed to confirm the result.

High protein concentration on plasma specimens interferes with this SHBG assay.

Albumin:

Albumin levels in serum or plasma are usually measured to assess nutritional status of the patient.

Albumin constitutes 55% to 65% of total plasma protein. It maintains oncotic plasma pressure, is involved in the transport and storage of a wide variety of ligands, and is a source of endogenous amino acids. Albumin binds various compounds, including bilirubin, calcium, long-chain fatty acids, toxic heavy metal ions, and numerous pharmaceuticals. Hypoalbuminemia may result from impaired synthesis due either to liver disease or due to reduced protein intake; increased catabolism as a result of tissue damage and inflammation; malabsorption of amino acids; and increased renal excretion (e.g. nephrotic syndrome).

PERFORMED: Sunday - Saturday

COLLECTION: **Testosterone:**
Serum separator tube (gold top preferred), plain red top tube, or lavender top tube (EDTA).

Unacceptable:

Specimens with the following conditions:

Heat-inactivated

Pooled

Grossly hemolyzed

Obvious microbial contamination

SHBG:

Serum separator tube (gold top preferred), green top plasma separator tube (lithium heparin), plain red top tube, sodium heparin tube (no gel), or lavender top (EDTA).

Unacceptable:

Na-Fluoride/K-Oxalate and Na-Citrate plasma tubes.

Specimens with the following conditions:

Heat-inactivated

Pooled

Grossly hemolyzed

Obvious microbial contamination

Cadaveric specimens and any other body fluids.

Albumin:

Serum separator tube (gold top preferred), plain red top tube, or green top plasma separator tube (lithium heparin).

SPECIMEN

PREPARATION:

Testosterone:

Centrifuge the serum separator tube and transport; if a plain red top tube or lavender top tube, centrifuge and aliquot serum or plasma (Min. 0.4 mL) into a standard transport tube.

SHBG:

Centrifuge the serum or plasma separator tube and transport; if plain red top, sodium heparin green top, or lavender top, centrifuge and aliquot serum or plasma (Min. 0.4 mL) into a standard transport tube.

	<u>Albumin:</u> Centrifuge the serum separator tube or plasma separator tube and transport; if a plain red top tube, centrifuge and aliquot serum (Min. 0.2 mL) into a standard transport tube.
STABILITY (FROM COLLECTION TO INITIATION OF TESTING):	<u>Testosterone:</u> After separation from cells: Ambient: 8 hours; Refrigerated (2 – 8°C): 7 days; Frozen (-20°C): Serum and plasma may be stored frozen for longer than 7 days. Specimen should not be subjected to more than 1 freeze thaw cycles. <u>SHBG:</u> After separation from cells: Ambient: 24 hours; Refrigerated (2 – 8°C): 8 days; Frozen: (-20°C): 3 months, Only 1 freeze/thaw cycle acceptable. <u>Albumin:</u> After separation from cells: Ambient: 24 hours; Refrigerated: 7 days; Frozen: Acceptable for longer storage
TRANSPORT:	Refrigerated for Testosterone, SHBG and Albumin
REFERENCE RANGE:	<u>Total Testosterone:</u> 21 – 49 years of age: 240 – 871 ng/dL ≥ 50 years of age: 221 – 716 ng/dL <u>Testosterone Free:</u> 18 years and older: 47 – 244 pg/mL <u>Testosterone % Free:</u> 18 years and older: 1.6 – 2.9% <u>SHBG:</u> 11.2 – 78.1 nmol/L <u>Albumin:</u> 3.2-4.8 g/dL
RESULTS REPORTED:	1 day
CPT CODE(S):	84403, 84270, 82040

PERFORMING LAB: med fusion

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