LABORATORY ALLIANCE of Central New York, LLC

Testosterone Testing for Adult Males: Total, Free, Bioavailable and SHBG Testing Options

Effective Tuesday, June 18, 2013, Laboratory Alliance of Central New York will offer in-house testing for sex hormone binding globulin (SHBG). Concurrently, we will also offer two new batteries for testosterone that include total testosterone by chemiluminescent immunoassay, SHBG and calculated values for bioavailable and/or free testosterone. Because of the sensitivity of the testosterone immunoassay (10 ng/dL), the target population for these tests is males, age 14 years and older.

The primary function of testosterone in the male is as a sex hormone; it is responsible for the development of male sex organs and secondary sexual characteristics such as increased muscle, bone mass, and the growth of body hair [1]. In addition, testosterone is important for health and well-being in both genders and plays an important role in bone metabolism, bone remodeling, and prevention of osteoporosis [2,3]. Testosterone in serum is largely protein bound to either SHBG or weakly to albumin. A small fraction of testosterone in serum remains as the free hormone (approximately 2%). For years it was believed that the free fraction of testosterone was the only biologically active fraction. However, it is now known that testosterone which is weakly bound to albumin readily dissociates in capillary beds and is readily available for tissue uptake. All non-SHBG bound testosterone (free and albumin-bound) is therefore considered bioavailable, which in males represents about 35% of the total testosterone. The free and bioavailable testosterone concentrations can be derived from mathematical expressions based on the total testosterone concentration, the SHBG concentration and the appropriate binding constants.

In adult men, there is a gradual and progressive decline in testosterone production starting between the fourth and sixth decade of life. This is associated with a simultaneous increase of SHBG levels and, therefore, bioavailable testosterone may decline more significantly than total testosterone. It is for this reason that determination of bioavailable and total testosterone is recommended for the diagnosis and monitoring of hypogonadism in adult males.

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With regard to total testosterone and the general interpretation of testosterone abnormalities in **males**:

- decreased testosterone levels indicate partial or complete hypogonadism. Serum testosterone levels are usually below the reference range.
- increased testosterone levels-
    1. In prepubertal boys, increased levels of testosterone are seen in precocious puberty. Further work-up is necessary to determine the cause(s) of precocious puberty.
    2. In adult men, testicular or adrenal tumors or androgen abuse might be suspected if testosterone levels exceed the upper limit of the normal range by more than 50%.

Automated immunoassays are widely used and are capable of accurately and precisely measuring the testosterone concentrations found in males. However, they lack the sensitivity and specificity to reliably measure the low testosterone concentrations found in women and children [4,5]. Liquid chromatography tandem mass spectrometry (LC/MS/MS) testosterone methods can achieve the required sensitivity and specificity for the low concentrations typical of females and children. They are, therefore, the recommended method when assaying testosterone levels in women and children. We will continue to refer specimens from females and males under age 14 to our reference laboratory for this more sensitive testing. Please note that this more sensitive testing is also available for males age 14 or older by special request to the laboratory.

The table below summarizes Laboratory Alliance's testosterone menu applicable to adult male patients.

Test Name	Test Code	Includes
Testosterone	TSTR	Total testosterone by immunoassay (limit of detection 10 ng/dL)
Testosterone, Free and Total	TSTRF	Total testosterone by immunoassay, SHBG, calculated free testosterone and % free testosterone.
Testosterone, Bioavailable	TSTRB	Total testosterone by immunoassay, SHBG, calculated bioavailable testosterone, free testosterone and % free testosterone.

Although SHBG may be ordered as an individual test, please note that SHBG should **not** be requested in addition to the testosterone batteries listed above.

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Test Codes:	
Total Testosterone	TSTR
Total and Free Testosterone	TSTRF
Total, Bioavailable and Free Testosterone	TSTRB
Specimen requirements:	One 5 mL gold top tube (SST). 2 mL serum required. Plasma (heparin) is also acceptable.
Storage and Transport:	Centrifuge within 2 hours of collection. Transport to laboratory refrigerated or ambient.
Stability:	Refrigerated: 2 days
Unacceptable Conditions:	
Testing Schedule:	Daily
CPT Codes:	
Total Testosterone	84403
Total and Free Testosterone	84403, 84270
Total, Bioavailable and Free Testosterone	84403, 84270
Billing Codes:	Total Testosterone = 1010097 Total & Free Testosterone = 1010459 Total, Bioavailable & Free Testosterone = 1010465

A complete set of age- and gender-specific reference intervals is available on our website at www.laboratoryalliance.com.

Questions regarding these tests may be directed to Cheryl Haskins, MS, MT(ASCP)SC, Manager of Chemistry and Referral Testing, at 315-410-7014 or cherylhaskins@lacny.com.

References:

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2. Bassil, N, Alkaade, S, Morley, JE. The benefits and risks of testosterone replacement therapy: a review. Ther Clin Risk Manag 2009; 5:427-48.
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4. Wang, C, Catlin, DH, Demers, LM, Starcevic, B, Swerdloff, R. Measurement of total serum testosterone in adult men: comparison of current laboratory methods versus liquid chromatography-tandem mass spectrometry. J Clin Endocrinol Metab 2004; 89:534-43.
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