OPTIMAL TESTOSTERONE TESTING SERVICES

LabCorp

Optimal Testosterone Testing – Helping you Select the Right Test for Each Patient

Testosterone is a steroid hormone that is commonly measured for various diagnostic purposes and can be measured by immunoassays or liquid chromatography and tandem mass spectrometry (LC/MS-MS). The most appropriate method for a particular patient depends on patient age, gender, the physician's intended use, and the performing laboratory's technical expertise.[1]

Men

Testosterone results can be used to evaluate hypogonadal men for primary or secondary testicular dysfunction. Male testosterone levels decrease with age (about 1% per year starting at age 30), and while this may be defined as testosterone deficiency or hypogonadism, it is generally a gradual decline in testosterone levels as men age, and is not a sudden loss of reproductive capability.[2] Changes seen with lowered testosterone and aging include decreases in bone mass, cognitive function, erectile function, libido, muscle strength, and sense of well-being.[2] Recent research suggests that maintaining the appropriate levels of testosterone may benefit men with osteoporosis, type 2 diabetes, cardiovascular disease, obesity, and depression.[3,4]

Women

In women, testosterone results can be used to evaluate conditions of androgen excess, such as PCOS (polycystic ovary syndrome), hirsutism, suspected androgen-producing neoplasm,[1,5,6] and conditions that may affect fertility, such as anovulation or amenorrhea with virilization. Testosterone measurement may also be helpful in menopausal women with suspected testosterone deficiency.[6] Androgen replacement therapy in postmenopausal women has also been studied as a means of boosting bone density and muscle mass.[7]

Children

Testosterone results in children can aid in the diagnosis and treatment of premature puberty, genetic diseases — such as congenital adrenal hyperplasia — and over-virilization or under-virilization at birth.[5] The recent epidemic of obesity in children has led to an increase in the assessment of androgen status in these patients because obesity has been associated with precocious puberty.[7]

Effective testosterone replacement therapies combined with increased consumer-faced advertising has raised general awareness to testing and treatment options.

Testosterone Testing Recommendations

For Men (test 004226)

- Generally, adult males' testosterone levels are typically at least 10 times higher than those of women and children.
- The Endocrine Society and the American Society for Andrology recommend using the total testosterone measurement — preferably obtained on more than one morning sample — as a screening test for hypogonadism in men and concluded that most direct immunoassays distinguish between testosterone concentrations found in classic hypogonadism and normal levels.[1,7,8]
- LabCorp's direct ECLIA testosterone immunoassay (test 004226) is indicated for use as an aid in screening for androgen dysfunctions in adult males. It is sensitive and accurate for this purpose and allows fast turnaround time for test results.[1]

For Women, Children, and Hypogonadal Men (test 070001)

- Direct immunoassays have been found to be adequate for identifying, but not accurately quantifying, elevated testosterone in women.[1]
- The Endocrine Society provides that testosterone determination in children be performed using assays with sufficient sensitivity and in conjunction with appropriate reference intervals.[1]
- LabCorp's testosterone by mass spectrometry assay (test 070001) can aid in the diagnosis of androgen dysfunction in females and children as well as for monitoring hypogonadal men. It offers high sensitivity and specificity, which are important when measuring very low testosterone concentrations.[1]

LabCorp: First National Lab to Achieve CDC Certification

A 2010 consensus statement endorsed by LabCorp as well as several professional societies calls for a "broad implementation of standardized testosterone measurements that are accurate, reliable, and comparable over time."[9] In 2011, the Centers for Disease Control and Prevention (CDC) began awarding certificates to laboratories that successfully met the performance criterion for testosterone testing.

LabCorp was the first national laboratory to achieve the prestigious CDC certification. LabCorp's total testosterone by liquid chromatography and tandem mass spectrometry (LC/MS-MS) assay [LabCorp test #070001] is currently certified by the CDC Hormone Standardization Program (HoST), and has maintained continuous certification since certificates were first issued in 2011. Certifications are published on the CDC Web site at www.cdc.gov/labstandards/doc/HoSt_Report.pdf.

CDC certification positions LabCorp's assay among the benchmark tests for testosterone. Furthermore, in a 2012 study published in *Clinical Chemistry* that analyzed five laboratories participating in the CDC Hormone Standardization (HoSt) program, LabCorp had the lowest desirable error rate among these labs, with 100% of samples meeting performance criteria.[10]

Test Name	Testosterone, Total, Serum
Test Number	004226
Reference Interval	
Adult Male*	264-916 ng/dL

*Adult male reference interval is based on a population of healthy nonobese males (BMI <30) between 19 and 39 years old.

Test Name	Testosterone, Total, Women, Children, and Hypogonadal Males, LC/MS-MS
Test Number	070001
Reference Interval	
Male	**(ng/dL)**
Premature (26-28 weeks) day 4	59.0-125.0
Premature (31-35 weeks) day 4	37.0-198.0
Newborns	75.0-400.0
1-7 months: Levels decrease rapidly the first week to 20.0-50.0 ng/dL, then increase to 60.0-400.0 ng/dL (mean = 190.0) between 20-60 days. Levels then decline to prepubertal range levels of <2.5-10.0 by seven months.	
Female	**(ng/dL)**
Premature (26-28 weeks) day 4	5.0-16.0
Premature (31-35 weeks) day 4	5.0-22.0
Newborns	20.0-64.0
1-7 months: Levels decrease during the first month to <10.0 and remain there until puberty.	
Prepubertal Children	**(ng/dL)**
Male (1-10 years)	<2.5-10.0
Female (1-9 years)	<2.5-10.0

Tanner Stage

Stage	Age	Male (ng/dL)
I	<9.8	<2.5-10.0
II	9.8-14.5	18.0-150.0
III	10.7-15.4	100.0-320.0
IV	11.8-16.2	200.0-620.0
V	12.8-17.3	350.0-970.0
Stage	**Age**	**Female (ng/dL)**
I	<9.2	<2.5-10.0
II	9.2-13.7	7.0-28.0
III	10.0-14.4	15.0-35.0
IV	10.7-15.6	13.0-32.0
V	11.8-18.6	20.0-38.0
Adult Male*		
>18 years	264.0-916.0	
Adult Female		
Premenopausal	10.0-55.0	
Postmenopausal	7.0-40.0	

*Adult male reference interval is based on a population of healthy nonobese males (BMI <30) between 19 and 39 years old.

References

1. Rosner W, Auchus RJ, Azziz R, et al. Utility, limitations, and pitfalls in measuring testosterone: An Endocrine Society position statement. *J Clin Endocrinol Metab.* 2007;92:405-413.
2. Ohl DA, Quallich SA. Clinical hypogonadism and androgen replacement therapy: An overview. *Urol Nurs*. 2006;26(4):253-259,269.
3. Kaufman JM, Vermeulen A. The decline of androgen levels in elderly men and its clinical and therapeutic implications. *Endocr Rev*. 2005;26:833-876.
4. Stanworth RD, Jones TH. Testosterone for the aging male; current evidence and recommended practice. *Clin Interv Aging*. 2008;3:25-44.
5. Taieb J, Mathian B, Millot F, et al. Testosterone measured by 10 immunoassays and by isotope-dilution gas chromatography—mass spectrometry in sera from 116 men, women, and children. *Clin Chem.* 2003;49:1381-1395.
6. Casson PR, Toth MJ, Johnson JV, Stanczyk FZ, Casey CL, Dixon ME. Correlation of serum androgens with anthropometric and metabolic indices in healthy, nonobese postmenopausal women. *J Clin Endocrinol Metab.* 2010;95:4276-4282.
7. Rollins G. The trials of testosterone testing: Immunoassays faulty in women and children, but what's the solution? *Clinical Laboratory News.* 2010;36:1,4-5.
8. Wang C, Nieschlag E, Swerdloff R, et al. Investigation, treatment, and monitoring of late-onset hypogonadism in males: ISA, ISSAM, EAU, EAA, and ASA recommendations. *J Androl.* 2009;30(1):1-9.
9. Rosner W, Vesper H; Endocrine Society, et al. Toward excellence in testosterone testing: A consensus statement. *J Clin Endocrinol Metab.* 2010;95:4542-4548.
10. Yun Y-M, Botelho JC, Chandler DW, et al. Performance criteria for testosterone measurements based on biological variation in adult males: recommendations from the partnership for the accurate testing of hormones. *Clin Chem.* 2012;58

LabCorp

Visit the online Test Menu at **www.LabCorp.com** for full test information, including CPT codes and specimen collection requirements.