Frequently Asked Questions
Testosterone by Mass Spectrometry

LabCorp offers total testosterone by liquid chromatography and tandem mass spectrometry (LC/MS-MS). Mass spectrometry provides a more accurate testosterone measurement at very low concentrations common among women, children, and hypogonadal men.[1] LabCorp's mass spec assay can be ordered using test number 070001 – Testosterone, total, women, children, and hypogonadal males, LC/MS-MS.

What is the benefit of performing testosterone by mass spectrometry?

Populations with low testosterone concentrations such as women, children, and hypogonadal males require more attention to an assay's analytical sensitivity and specificity. This requirement has limited the clinical utility of some traditional assays (RIA, ELISA, ECLIA) for these patient populations.[1] One method that may offer an appropriate level of specificity for these populations is high-performance liquid chromatography and tandem mass spectrometry.[1]

A 2010 consensus statement provides guidance regarding testosterone testing. This statement calls for a "broad implementation of standardized testosterone measurements that are accurate, reliable, and comparable over time."[2]

The consensus statement has been endorsed by[2]

- American Association for Clinical Chemistry
- American Association of Clinical Endocrinologists
- Androgen Excess/PCOS Society
- American Society for Bone and Mineral Research
- American Society for Reproductive Medicine
- American Urological Association
- Association of Public Health Laboratories
- The Endocrine Society
- Laboratory Corporation of America (LabCorp)
- North American Menopause Society
- Pediatric Endocrine Society

As a result of this consensus statement, the Centers for Disease Control and Prevention (CDC) initiated a project for assay standardization and oversight.[2] LabCorp's total testosterone by liquid chromatography and tandem mass spectrometry (LC/MS-MS) is certified by the Centers for Disease Control (CDC) Hormone Standardization (HoSt) Program. LabCorp's certification is published on the CDC Web site at www.cdc.gov/labstandards/doc/HoSt_Report.pdf. CDC certification positions LabCorp's methodology among the benchmark assays for testosterone measurement.

What is the test number for the mass spec assay?

The test number for the mass spectrometry assay for women, children, or hypogonadal men is 070001. An ECLIA assay (test number 004226) is also available for use with screening adult men.

What is the intended use for the two testosterone assays offered by LabCorp?

The LC/MS-MS assay (test 070001) can aid in diagnosis of androgen dysfunction in females and children as well as for monitoring adult males diagnosed with hypogonadism. It is more specific when measuring testosterone concentrations.[1]

The direct ECLIA testosterone immunoassay (test 004226) is appropriate for use as an aid in diagnosis of androgen dysfunctions in adult males. It is sufficiently sensitive and accurate for this purpose and allows a fast turnaround time of test results.[3]

Where is the mass spectrometry testing performed?

This testing is performed at LabCorp's Center for Esoteric Testing and Esoterix's Endocrine Sciences laboratory.

Is the mass spec assay available in a profile?

Please refer to the chart below for profiles with the mass spec assay.

Test Name	Profile Test Number
Testosterone, Free, Equilibrium Ultrafiltration With Total Testosterone by LC/MS-MS	070038
Testosterone, Free (Direct) With Total Testosterone by LC/MS-MS	070195
Testosterone, Free and Weakly Bound, With Total Testosterone by LC/MS-MS	070282

LabCorp
Laboratory Corporation of America

Frequently Asked Questions
Testosterone by Mass Spectrometry

What are the reference intervals using mass spectrometry?

The CDC's Hormone Standardization Project (HoSt project) is guiding testosterone standardization, which will enable harmonization of testosterone results across methodologies and laboratories.

LabCorp's current reference intervals for the mass spectrometry assay are as follows:

Children

	Male Range (ng/dL)	Female Range (ng/dL)
Premature Infants		
26 to 28 Weeks, Day 4	59.0-125.0	5.0-16.0
31 to 35 Weeks, Day 4	37.0-198.0	5.0-22.0
Full-term Infants		
Newborns	75.0-400.0	20.0-64.0
Males 1 to 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 of <2.5-10.0 by seven months.	
Females 1 to 7 Months	Levels decrease during the first month to <10.0 ng/dL and remain there until puberty.	
Prepubertal Children	**1 to 10 Years**	**1 to 9 Years**
	<2.5-10.0	<2.5-10.0

Puberty

Tanner Stage	Age (Years)	Range (ng/dL)	Mean (ng/dL)	Tanner Stage	Age (Years)	Range (ng/dL)	Mean (ng/dL)
Males				**Females**			
1	<9.8	<2.5 – 10.0	4.9	1	<9.2	<2.5 – 10.0	4.9
2	9.8 – 14.5	18.0 –150.0	42.0	2	9.2 – 13.7	7.0 – 28.0	18.0
3	10.7 – 15.4	100.0 – 320.0	190.0	3	10.0 – 14.4	15.0 – 35.0	25.0
4	11.8 – 16.2	200.0 – 620.0	372.0	4	10.7 – 15.6	13.0 – 32.0	22.0
5	12.8 – 17.3	350.0 – 970.0	546.0	5	11.8 – 18.6	20.0 – 38.0	28.0

Adults

≥ 18 Years	Range (ng/dL)
Males	350.0 - 1030.0
Females	
Premenopausal	10.0 - 55.0
Postmenopausal	7.0 - 40.0

References

1. Rosner W, Auchus RJ, Azziz R, Sluss PM, Raff H. Utility, limitations, and pitfalls in measuring testosterone: an Endocrine Society Position Statement. *J Clin Endocrinol Metab.* 2007;92:405-413.
2. Rosner W, Vesper H on behalf of the Endocrine Society and endorsing organizations. Toward Excellence in Testosterone Testing: A Consensus Statement. *J Clin Endocrinol Metab.* 2010;95:4542-4548.
3. 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 Andrology*. 2009;30:1-9.

LabCorp
Laboratory Corporation of America

www.LabCorp.com