

## Testosterone Test Information

Testosterone (T), is a steroid hormone belonging to the class of androgens. It is the major male sex hormone and plays a key role in the development of the male reproductive organs and the promotion of secondary sexual characteristics. It is produced primarily by the testicles of males and, to a lesser extent, the ovaries of females. It is synthesized from cholesterol and circulates in human blood mostly bound strongly to sex hormone binding globulin (SHBG) and, to a lesser extent, to albumin. Only ~2% of testosterone circulates in the biologically-active 'free' form. In most cases the measurement of serum total testosterone (TT) is sufficient for clinical diagnostic purposes; however, if the free testosterone (Free T) level is needed for clinical decision-making, it can be measured directly or calculated.

Measurement of TT has important significance in various clinical scenarios. For men, the testosterone level is crucial to evaluate hypogonadism and prostate cancer onset in aging men. For women, the measurement of testosterone is used in the investigation of androgen disorders (eg. hirsutism) and androgen-secreting tumors (eg. ovarian cancer). For children, serum testosterone concentration is an important indicator of pubertal stage development.

Human serum TT levels have a wide sex and age-based variability. The normal T range for healthy men is 300-1000 ng/dL (2) and is much lower in women, children, and men with testosterone deficiency. Traditional measurements of TT are based on radio-immunoassays (RIA) that suffer from limited specificity and a large positive bias in the low T concentration range (eg. women and children). Liquid chromatography-tandem mass spectrometry (LC-MS/MS) offers superior analytical selectivity, sensitivity and dynamic range, and has recently become the gold standard of serum TT quantification for routine clinical evaluation (3). Our lab offers a sensitive stable-isotope dilution LC-MS/MS assay of serum TT based on organic solvent liquid-liquid extraction method. For more information, call the lab at 513-636-4203.

### Sample Type:

Serum (Red, No Gel)

### Volume:

1.5 mL

1.0 mL (minimum)

### Specimen Preparation:

Spin/pour off, freeze ASAP. Refrigerated samples acceptable if less than 7 days.

### Unacceptable specimens:

Separator tubes or gel; red cells when pouring off sample.

### Stability:

**Ambient:** 24 hours

**Refrigerated:** 7 days

**Frozen:** 6 months

### Methodology:

**TT:** Liquid chromatography-tandem mass spectrometry (LC-MS/MS)

**Free T:** Calculated from TT and SHBG

### Reporting Units:

Quantitative: ng/mL

### LC-MS/MS Calibration Range:

1 – 1000 ng/dL

### Reference Interval:

See table

### Shipping Conditions:

Frozen (dry ice), next day.

### Testing Schedule:

Mon, Thu, 1st Shift (for testing outside this schedule, please call 513-636-4203). **Turnaround time:** 2 – 7 days.

### CPT Code:

84403

### Contact Information:

Clinical Mass Spectrometry

Tel: 513-636-4203

Fax: 513-803-5014

Email: [pathology@cchmc.org](mailto:pathology@cchmc.org)

Website: <https://www.cincinnatichildrens.org/mass-spec>

### Shipping Address:

Clinical Mass Spectrometry Facility, MLC 7019

Department of Pathology and Laboratory Medicine

Cincinnati Children's Hospital Medical Center

3333 Burnet Avenue

Cincinnati, Ohio 45229

### References:

1. Vermeulen A. et al. A critical evaluation of simple methods for the estimation of free testosterone in serum. *J. Clin Endocrinol Metab* 1999 (84) 3666-3672
2. Matsumoto AM. And Bremner WJ. Editorial: serum testosterone assays-accuracy matters. *J. Clin Endocrinol Metab* 2004 (89) 520-524
3. Ketha H. et al. Clinical applications of LC-MS sex steroid assays: Evolution of methodologies in the 21st century. *Curr Opin Endocrinol Diabetes Obes.* 2014 (21) 217-226.