



## Recommendation to Order a Standardized Assay to Measure Serum Total Testosterone Concentrations



Avalon Healthcare Solutions has become a member of the [Partnership for the Accurate Testing of Hormones \(PATH\)](#), a national network of clinical, medical, laboratory and public health organizations and experts working to improve patient care through the universal use of standardized accurate and reliable hormone tests in healthcare and research.

Because there is a well-established Centers for Disease Control and Prevention (CDC) standardization program, numerous standardized assays available, and a harmonized reference range for total testosterone, Avalon strongly recommends that providers and payers respectively order and reimburse only standardized total testosterone assays for laboratory evaluation of patients.

## WHAT IS A STANDARDIZED TOTAL TESTOSTERONE ASSAY?

### Standardized total testosterone assays are:

- Accurate – total testosterone measurements are highly comparable to reference standard (“gold standard”) values measured by a reference method
- Reliable – total testosterone measurements are highly similar on repeated measurements of the same sample
- Comparable – total testosterone measurements in the same sample are similar in different assays and laboratories and stable over time

**At present, most total testosterone assays are inaccurate and not standardized, resulting in:**

- Over- and under-diagnosis of hypogonadism (low testosterone)
  - Total testosterone values and reference ranges (“normal ranges”) that differ from assay-to-assay
  - Inappropriate treatment with testosterone and exposure to potential side effects
  - Need to repeat testing when there is a change in practitioner or testing laboratory
- Increased healthcare costs
- Inconsistent clinical practice guidelines
  - Inability to translate research findings to patient care

**CDC Total Testosterone Standardization Program**

- Developed a reference method and standards for testosterone
- Reference standards are used to standardize (“calibrate”) total testosterone assays
- Regular testing of assay accuracy to within 6.4% of gold standard values
- Samples containing testosterone levels in the female to male range are used to test testosterone assay accuracy

- Quarterly certification of testosterone assays that perform adequately
- Most commercial reference laboratory testosterone assays are CDC-certified ([https://www.cdc.gov/labstandards/hs\\_certified\\_participants.html](https://www.cdc.gov/labstandards/hs_certified_participants.html))

## **WHY DOES AVALON RECOMMEND ORDERING A CDC-CERTIFIED TOTAL TESTOSTERONE ASSAY?**

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**To improve patient care by:**

- Using the most accurate and reliable standardized testosterone assays for making diagnoses and clinical decisions
- Permitting the use of a consistent reference range for adult men based on standardized testosterone measurements
- Resulting in a more accurate diagnosis of hypogonadism and appropriate use of testosterone treatment
- Avoiding the need for repeat testosterone testing and its associated clinical uncertainty
- Permitting more direct translation of research findings that used standardized testosterone assays (such as from the Testosterone Trials) to patient care and clinical practice guidelines (such as the Endocrine Society testosterone treatment guidelines)

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### **About Avalon Healthcare Solutions**

Avalon is the world’s first Lab Insights company pioneering a new era of value-driven care by unlocking the potential of lab results to generate actionable lab-driven insights in real time to proactively ensure appropriate care, enhance clinical outcomes, and reduce overall costs. For more information about Avalon, please visit [www.avalonhcs.com](http://www.avalonhcs.com).