

CDC HoSt-TT Certification for Siemens Healthineers Total Testosterone Test Expands Patient Access to Gold Standard Equivalent Results

- **The Atellica TSTII Testosterone assay is the only immunoassay with CDC HoSt-TT Certification**
- **Certification reaffirms assay results are aligned with specialized mass spectrometry testing method**
- **The immunoassay test is a broadly available, economical option for patients and laboratories**

Siemens Healthineers announced its Atellica IM Testosterone II (TSTII) assay has achieved certification through the Centers for Disease Control and Prevention (CDC) Hormone Standardization Program for Total Testosterone (HoSt-TT). This certifies that the Atellica IM TSTII immunoassay's test results are equivalent to high performance liquid chromatography coupled with tandem mass spectrometry, which is regarded as the gold-standard analytical approach^{1,2}. The Atellica IM TSTII assay, available on the Atellica IM and Atellica CI Analyzers, is the only fully automated immunoassay with CDC HoSt-TT certification, which it has maintained continuously since 2019³. An evaluation of the assay's performance was recently published in [*The Journal of Clinical Endocrinology & Metabolism*](#).

Testosterone is a key steroid hormone with essential roles in sexual development, reproductive function, musculoskeletal health, and bone metabolism. Accurate measurement of testosterone is clinically important, as abnormal levels may be associated with a wide range of endocrine, metabolic, reproductive, and oncologic conditions.² In clinical and research settings, total testosterone measurements are often considered alongside other biochemical and clinical factors when evaluating androgen status. High-quality, standardized testosterone assays play an important role in supporting consistent measurement and interpretation across diverse patient populations, including male, female, and pediatric patients.

"For women and children, testosterone levels are naturally low, which makes accurate measurement challenging," said Ross Molinaro, PhD, head of Medical Value and Evidence for Diagnostics at Siemens Healthineers. "The Atellica IM TSTII Testosterone assay is currently the only fully automated immunoassay with sustained CDC HoSt-TT certification, offering a suitable and widely used routine method that is alternative to an otherwise specialty testing method, enabling clinicians to confidently support more patients."

Certification through the HoSt-TT program ensures traceability, minimizes variability, and supports compliance with Endocrine Society and American Urological Association guidelines⁴. Ongoing certification ensures longitudinal consistency and reliable clinical interpretation of total testosterone results.

“The CDC’s Clinical Hormone Standardization Programs standardize the total testosterone assay so that results are accurate, comparable, and clinically meaningful wherever they are performed, said Scott D. Isaacs, MD, FACP, FACE, adjunct professor for the Department of Medicine at Emory University School of Medicine. “By calibrating assays to a common reference method and enforcing stringent performance criteria, CDC HoSt-TT reduces inter-laboratory variability. In clinical practice, this level of standardization improves the quality of care. When I review a total testosterone result, I can trust that it reflects the same analytical standard regardless of where it was performed, allowing for more consistent diagnosis and treatment decisions.”

More information about the Atellica IM TSTII assay is available [here](#).

1 French D., (2023) [Clinical utility of laboratory developed mass spectrometry assays for steroid hormone testing](#)

2 Cook Botelho, J. et al. (2013) [Isotope-Dilution Liquid Chromatography–Tandem Mass Spectrometry Candidate Reference Method for Total Testosterone in Human Serum](#)

3 [Certified Total Testosterone Assays](#) | CDC

4 Jieli Li, et al. (2026) [Evaluation of the Siemens Healthineers Atellica TSTII testosterone assay in the CDC HoSt-TT Program](#)

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