LABupdate

Testosterone Reference Interval Change for Adult Males

In 2010, a group of professional associations, government agencies and commercial entities endorsed a consensus effort to improve the accuracy of total testosterone testing. There were several objectives outlined within the consensus statement, including:

- Develop standardized testosterone assays[1]: The Centers for Disease Control and Prevention (CDC) together with the Endocrine Society established the Hormone Standardization (HoSt) program[2] in 2010
  - The CDC HoSt program has issued annual certificates to laboratories that demonstrate performance within the established criteria
  - HoSt certification evidences harmonized testosterone results across CDC certified methods

- Establish standardized testosterone reference intervals by age and gender[1]: Travison et al.[2] published a population-based study at the beginning of 2017 which:
  - Evaluated more than 9,000 adult male patients from different geographic regions of the United States and Europe
  - Included 1,185 adult males between 19 and 39 years old, with a BMI less than 30
  - Utilized testosterone assays harmonized to the CDC reference method
  - **Standardized testosterone reference interval for nonobese adult males (BMI <30) which was calculated as 264 – 916 ng/dL**

Based on this study, LabCorp's serum testosterone assays, including profiles that contain testosterone measurements, will use the new standardized testosterone reference interval for adult males.

LabCorp's Available Testosterone Assays

Total Testosterone by LC/MS-MS	
Testosterone, Total, Women, Children, and Hypogonadal Males, LC/MS-MS	070001
Available Profiles (using LC/MS-MS)	
Testosterone, Free, Equilibrium Ultrafiltration with Total Testosterone, LC/MS-MS	070038
Testosterone, Free, Direct with Total Testosterone, LC/MS-MS	070195
Testosterone, Free and Weakly Bound, with Total Testosterone, LC/MS-MS	070282
Testosterone Free, Profile II (includes albumin; free testosterone, calculated; SHBG; testosterone by LC/MS-MS)	070130
Testosterone, Free, Mass Spectrometry/ Equilibrium Dialysis (Endocrine Sciences)	500726

Total Testosterone by ECLIA	
Testosterone, Total	004226
Available Profiles (using ECLIA)	
Testosterone, Free, Equilibrium Ultrafiltration With Total Testosterone	081786
Testosterone, Free, Direct with Total Testosterone	140103
Testosterone, Free and Weakly Bound	143255
Testosterone Free, Profile I (includes albumin; free testosterone, calculated; SHBG; testosterone by ECLIA)	140226

Saliva Specimens	
Salivary Testosterone, LC/MS-MS (Endocrine Sciences)	503765

References

1. Rosner W, Vesper H; Endocrine Society, et al. Toward excellence in testosterone testing: A consensus statement. *J Clin Endocrinol Metab.* 2010 Oct; 95(10):4542-4548. PubMed 20926540
2. Travison TG, Vesper HW, Orwoll E, et al. Harmonized reference ranges for circulating testosterone levels in men of four cohort studies in the United States and Europe. *J Clin Endocrinol Metab* 2017 April; 102(4):1161-1173. doi:10.1210/jc.2016-2935

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