

CDC Hormone Standardization Program (CDC HoSt)

Certified Total Testosterone Procedures

(UPDATED 06/2019)

- The following laboratories have successfully met the performance criterion of $\pm 6.4\%$ mean bias when compared to the CDC reference measurement procedure for total testosterone.
- CDC HoSt Program certifies the performance of participants within the concentration range of 2.50-1,000 ng/dL for total testosterone.
- It is not the intent of the CDC HoSt Program to certify each lot of reagents. Laboratories are awarded certificates for successfully meeting bias criterion using specific methods that consist of different reagent lots and calibrator lots.
- Analytical performance in CDC HoSt Program is assessed using human serum. The measurement procedures may have different accuracy and precision with other specimen types, such as plasma.
- Certification is valid for one year. During that year, it is the responsibility of the participant to ensure that the results of their method remain consistent throughout the year, between lots, and over the measurement range reported.
- The analytical performance evaluation used in certification is for testing performed in patient care. Therefore, this certification does not imply suitability of a participant as a calibration laboratory or the procedure as a metrological reference measurement procedure.

There are two tables. Table 1 is the list of assays that are currently certified with the CDC HoSt Program. Table 2 is the list of assays that have been certified previously but are not currently certified. Participants are listed in alphabetical order.

Each table includes information about certified/previously certified participants, including name, measurement principle, method identifier, measurement range, certification date, pass rate of individual samples, and contact information.

“Method identifier” is an internal code used by the participant to represent the method used for certification.

“Measurement range” is the participants’ reported analytical measurement range (AMR) and is not the certification range.

“Certification date” includes historical certification information and gaps between years do not always indicate the assay’s failure to meet certification criteria.

“Individual samples pass rate” is the percentage of individual samples out of the 40 provided that met the certification criteria of $\pm 6.4\%$ bias. This information was provided starting in February 2017.

Table 1: Currently Certified Assays including their certification history (for previously certified participants with no current certificate, see Table 2)

Participant	Measurement Principle	Method Identifier	Total Testosterone Measurement Range (ng/dL)	Certification Date (active for 1 year)	Individual Samples Pass Rate (%)	Participant's Contact Information
Brigham Research Assay Core (BRAC) Laboratory at Harvard Medical School Boston, MA	LC/MS/MS ⁺	Serum Total Testosterone	1.00–2,000 (>2,000 with dilution)	Feb 2019 Feb 2018 Feb 2017 Aug 2016 Aug 2015 Feb 2014 Feb 2012 Feb 2011	68 90 70 N/A N/A N/A N/A N/A	Dr. Shalender Bhasin sbhasin@bwh.harvard.edu (617) 525-9040 Liming Peng Lpeng2@bwh.harvard.edu (617) 525-9048
BioReference Laboratories, an OPKO Health Company Elmwood Park, NJ	LC/MS/MS ⁺	Total Testosterone	1-4,000	Nov 2018	78	Hashim Othman, Ph.D. hothman@bioreference.com
Clinical Chemistry Branch CDC Atlanta, GA	LC/MS/MS ⁺	Total Testosterone in Serum (1036)	0.57-12,800	Feb 2019	92	Lumi Duke, MS LDuke@cdc.gov (770) 488-4126
Covance Central Laboratories Services, Inc. Indianapolis, IN	LC/MS/MS ⁺	Serum Total Testosterone	2.00–8,000	Feb 2019 Feb 2018 Feb 2017 Feb 2016 Feb 2015 Feb 2014 Feb 2013 Feb 2012	62 74 65 N/A N/A N/A N/A N/A	Cristina Hedin, MS 8211 Scicor Drive Indianapolis, IN 46214 cristina.hedin@covance.com (317) 273-7842
Endocrine and Metabolic Research Laboratory at Los Angeles Biomedical Research Institute Torrance, CA	LC/MS/MS ⁺	TDHT	2.0–2,000	May 2019 May 2018 May 2016 May 2015 May 2013 May 2012 May 2011	42 60 N/A N/A N/A N/A N/A	Dr. Christina Wang wang@labiomed.org (310) 222-2503
Mayo Clinic Rochester, MN	LC/MS/MS ⁺	Total Testosterone in Serum	7.00-2,000	Feb 2018	68	Sue Reicks Reicks.sue@mayo.edu (507) 284-9274
LabCorp Calabasas Hills, CA	LC/MS/MS ⁺	#070001 Testosterone, Total, Women,	2.50–5,000	Aug 2018 Aug 2017 Aug 2016	100 65 N/A	Dr. Andre Valcour ValcouA@labcorp.com (336) 436-3854

		Children, and Hypogonadal Males, LC MS/MS	(250,000 with validated dilution)	Aug 2015 Aug 2014 Aug 2013 Aug 2012 Aug 2011	N/A N/A N/A N/A N/A	Dr. Walt Chandler Chandld@labcorp.com (818) 867-1370
Molecular Epidemiology Biomarker & Research Laboratory at the University of Minnesota Minneapolis, MN	LC/MS/MS†	Total Testosterone in Serum	4–2,000	Feb 2019 Feb 2017 Feb 2016	90 73 N/A	Myron Gross PhD Gross001@umn.edu (612) 624-5417
Pathology Associates Medical Laboratory, LLC Spokane, WA	LC/MS/MS†	Testosterone (LCMSMS)	2.5 – 1,000 (2.5 – 4,000 with validated dilution)	Feb 2019 Feb 2018 May 2017 Feb 2015 Nov 2013	65 75 75 N/A N/A	Carissa Schmitz MLS(ASCP)CM cschmitz@paml.com (509) 755-8358
Quest Diagnostics Nichols Institute of Valencia, Inc. Valencia, CA	LC/MS/MS†	Serum Total Testosterone	2–2,000 (10,000 with dilution)	Feb 2019 Feb 2018 Feb 2017 Nov 2015	75 74 60 N/A	Amit Ghoshal PhD Amit.K.Ghoshal@QuestDiagnostics.com Quest Diagnostics Nichols Institute Valencia, Inc. (661) 799-6204
SCIEX Diagnostics Framingham, MA	LC/MS/MS†	Total Testosterone	1-2,000	Feb 2019 Feb 2018	75 88	Theresa Irvine Theresa.Irvine@sciex.com 508-383-7409
Siemens Healthcare Diagnostics Newark, DE	Chemiluminescence Immunoassay	Serum Total Testosterone	8–1,000	Aug 2018 Aug 2017 Aug 2016	28 20 N/A	Dr. Craig Hixson craig.hixson@siemens.com (302) 631-7540
Siemens Healthcare Diagnostics Tarrytown, NY	Chemiluminescence Immunoassay	ADVIA Centaur® Testosterone II Assay	7.0-1500	Feb 2019	32	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477

† LC/MS/MS – Liquid Chromatography Tandem Mass Spectrometry

‡ GC/MS/MS – Gas Chromatography Tandem Mass Spectrometry

N/A not available. Note: Pass Rates are provided as of February 2017

Table 2: Previously certified assays with no current certification

Participant	Measurement Principle	Method Identifier	Total Testosterone Measurement Range (ng/dL)	Certification Date (active for 1 year)	Individual Samples Pass Rate (%)	Participant's Contact Information
ARUP Laboratories Salt Lake City, UT	LC/MS/MS [†]	Total Testosterone in Serum	1.00–2,500	Nov 2017 Nov 2016 Nov 2015 Nov 2014 May 2013 May 2012	70 N/A N/A N/A N/A N/A	Canary Tennison canary.tennison@aruplab.com 801-583-2787 x2893
Clinical Chemistry Branch CDC Atlanta, GA	LC/MS/MS [†]	Total Testosterone in Serum (1033)	0.75–1,400 (0.75–3,000 with dilution)	Nov 2017 Nov 2016 Nov 2015	93 N/A N/A	Lumi Duke, MS LDuke@cdc.gov (770) 488-4126 Hui Zhou, PhD HZhou2@cdc.gov (770) 488-4861
Clinical Chemistry Sahlgrenska University Hospital - Gothenburg, Sweden	GC/MS/MS [‡]	Serum Total Testosterone	1.25–1,000	Nov 2016 Aug 2015 Aug 2014 Aug 2013	N/A N/A N/A N/A	Dr. Henrik Ryberg Henrik.ryberg@vgregions.se +46 708 654482
Laboratory Alliance of Central New York, LLC	LC/MS/MS [†]	TSTLC Testosterone by LC/MS/MS, Females or Children	2.50-1,000	Aug 2014	N/A	Dr. Roy Huchzermeier royhuchzermeier@lacny.com (315)410-7221 Cheryl Haskins cherylhaskins@lacny.com (315)410-7014
Roche Diagnostics GmbH	Chemiluminescence Immunoassay	Elecsys Testosterone II (05200067)	2.50-1,500	Aug 2014 Aug 2013 Aug 2012 Aug 2011	N/A N/A N/A N/A	
SCIEX Diagnostics Framingham, MA	LC/MS/MS [†]	Total Testosterone II	1-2,000	May 2018	78	Theresa Irvine Theresa.Irvine@sciex.com 508-383-7409
ZRT Laboratory	LC/MS/MS [†]	Serum Total Testosterone-Multi-Analyte Method	5.0-1,000	Nov 2014 Nov 2013	N/A N/A	David T. Zava, Ph.D. dzava@zrtlab.com David W. Kimball, M.S. dwkimball@zrtlab.com (866)600-1636

† LC/MS/MS – Liquid Chromatography Tandem Mass Spectrometry
‡ GC/MS/MS – Gas Chromatography Tandem Mass Spectrometry
N/A not available. Note: Pass Rates are provided as of February 2017