

CDC Hormone Standardization Program (CDC HoSt)

Certified Total Testosterone Assays

From 2019 Q4 and forward

(UPDATED 05/2023)

CDC HoSt started quarterly certification from November 2019 shipment.

See https://www.cdc.gov/labstandards/csp/pdf/hs/CDC_Certified_Testosterone_Procedures-508.pdf for previous list of certified assays.

- The following assays have successfully met the performance criterion of $\pm 6.4\%$ mean bias when compared to the CDC reference measurement procedure for total testosterone.
- It is not the intent of the CDC HoSt Program to certify each lot of reagents. Participants 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 quarter from the certification date. It is the responsibility of the participant to ensure that the results of the assay remain consistent, 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.

Each table includes information about certified assays, including participant name, measurement principle, assay identifier, assay measurement range, certification measurement range, certification date, individual samples pass rate, and contact information.

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

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

“Certification Measurement Range” is the concentration range the of the samples used for HoSt certification.

“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.

Note: The $\pm 6.4\%$ mean bias used for certification can be considered the allowable calibration bias. Certification indicates that the assay is calibrated to meet those limits. Due to differences in test selectivity, measurements on individual samples can exceed the calibration bias. Therefore, the individual sample pass rate provides some information about the selectivity of a test that meets the calibration criteria.

CDC CSP suggests manufacturers and developers to participate in HoSt for certifications. The end-users or secondary location of an LDT may participate in Accuracy-based Monitoring Programs (CDC AMP) to verify performance. This document also indicates secondary LDT locations that are participating in AMP (Table 2).

Table 1: Currently Certified Assays including their certification history

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date (active for 1 quarter)	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	7.71 - 753	Q4 2022	68	Kayla West Kayla.west@aruplab.com 801-583-2787 x2893
				7.71 - 753	Q3 2022	60	
				10.1 - 753	Q2 2022	42	
				10.1 - 736	Q1 2022	50	
				10.1 - 736	Q4 2021	38	
				8.53 - 680	Q3 2021	55	
				7.71 - 680	Q2 2021	75	
				7.71 - 680	Q1 2021	85	
				7.71 - 941	Q4 2020	90	
				7.71 - 941	Q3 2020	92	
				8.77 - 941	Q2 2020	72	
				9.63 - 941	Q1 2020	70	
				5.70 - 840	Q4 2019	52	
BioReference Laboratories, an OPKO Health Company Elmwood Park, NJ	LC/MS/MS ⁺	Total Testosterone	1 - 4,000	7.71 - 821	Q3 2020	62	Hashim Othman, Ph.D. hothman@bioreference.com
				8.49 - 915	Q2 2020	72	
				8.49 - 915	Q1 2020	68	
				8.49 - 915	Q4 2019	75	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date (active for 1 quarter)	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)	10.9 - 840	Q4 2022	70	<p>Dr. Shalender Bhasin sbhasin@bwh.harvard.edu (617) 525-9040</p> <p>Liming Peng Lpeng2@bwh.harvard.edu (617) 525-9048</p>
				8.53 - 840	Q3 2022	78	
				7.71 - 753	Q2 2022	90	
				7.71 - 941	Q1 2022	92	
				7.71 - 941	Q4 2021	82	
				7.71 - 941	Q3 2021	72	
				8.77 - 941	Q2 2021	72	
				8.77 - 680	Q1 2021	68	
				8.77 - 941	Q4 2020	68	
				8.77 - 941	Q3 2020	57	
				8.77 - 941	Q2 2020	50	
				7.71 - 941	Q1 2020	55	
				5.70 - 915	Q4 2019	57	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date <i>(active for 1 quarter)</i>	Individual Samples Pass Rate (%)	Participant's Contact Information
Clinical Chemistry Branch CDC Atlanta, GA	LC/MS/MS ⁺	Total Testosterone in Serum (1036)	0.57 - 12,800	7.71 - 680	Q4 2022	90	Lumi Duke, MS LDuke@cdc.gov (770) 488-4126
				7.71 - 629	Q3 2022	92	
				7.71 - 651	Q2 2022	88	
				8.53 - 651	Q1 2022	90	
				8.53 - 680	Q4 2021	90	
				8.53 - 840	Q3 2021	90	
				11.0 - 840	Q2 2021	90	
				8.77 - 840	Q1 2021	92	
				8.77 - 941	Q4 2020	95	
				8.49 - 941	Q3 2020	92	
				8.49 - 941	Q2 2020	98	
				8.49 - 941	Q1 2020	98	
				8.49 - 915	Q4 2019	98	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Covance Central Laboratories Services, Inc. Indianapolis, IN	LC/MS/MS ⁺	Serum Total Testosterone	2.00 - 8,000	9.51 - 941	Q4 2022	87	Cristina Hedin, MS 8211 Scicor Drive Indianapolis, IN 46214 cristina.hedin@covance.com (317) 273-7842
				9.51 - 941	Q3 2022	79	
				8.77 - 941	Q2 2022	82	
				8.77 - 769	Q1 2022	82	
				7.71 - 840	Q4 2021	78	
				7.71 - 840	Q3 2021	88	
				7.71 - 840	Q2 2021	78	
				7.71 - 840	Q1 2021	78	
				8.77 - 941	Q4 2020	82	
				8.77 - 941	Q3 2020	78	
				8.77 - 941	Q2 2020	85	
				7.71 - 941	Q1 2020	85	
				7.71 - 753	Q4 2019	80	
Covance Central Laboratories Services, Inc. Geneva, Switzerland	LC/MS/MS ⁺	Total Testosterone	2.00 - 8,000	12.0 - 629	Q4 2022	88	Gaelle Gilbert gaelle.gilbert@covance.com 0041 (0) 58 822 7656
				12.0 - 941	Q3 2022	95	
				12.0 - 941	Q2 2022	98	
				12.2 - 941	Q1 2022	90	
				12.2 - 941	Q4 2021	95	
				12.2 - 769	Q3 2021	75	
				12.2 - 769	Q2 2021	70	
				8.77 - 821	Q1 2021	75	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Diagnostic Laboratory for Endocrinology, Erasmus University Medical Center Rotterdam, The Netherlands	LC/MS/MS ⁺	Serum Testosterone	2 - 1,093	7.71 - 821 7.71 - 941 7.71 - 941 8.77 - 941 7.71 - 941 7.71 - 769 7.71 - 769 7.71 - 736 8.77 - 753 8.49 - 821 8.49 - 821 8.49 - 840 8.49 - 840	Q4 2022 Q3 2022 Q2 2022 Q1 2022 Q4 2021 Q3 2021 Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	90 88 90 92 80 85 70 68 78 78 92 92 95	S.A.A. van den Berg s.a.vandenberg@erasmusmc.nl S.S. Panchoe - Ramcharan s.panchoe@erasmusmc.nl
Endocrine and Metabolic Research Laboratory at Los Angeles Biomedical Research Institute Torrance, CA	LC/MS/MS ⁺	TDHT	2.0 - 2,000	7.71 - 941 11.0 - 769 8.53 - 753 8.53 - 753 8.53 - 736 8.53 - 736 8.77 - 941 8.77 - 941 3.66 - 941	Q4 2022 Q1 2022 Q4 2021 Q3 2021 Q2 2021 Q1 2021 Q4 2020 Q2 2020 Q1 2020	50 50 52 65 68 50 52 48 70	Dr. Christina Wang wang@lundquist.org (310) 222-2503

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
GC Labs Yongin-si, Gyeonggi-do, Republic of Korea	LC/MS/MS ⁺	Total Testosterone	0.8 - 5188.5	8.53 - 821 8.77 - 941 8.53 - 736	Q4 2022 Q3 2022 Q2 2022	92 95 88	Sung-Eun Cho, M.D., Ph.D secho1206!!@gclabs.co.kr Jung-Sun Han jshan@gclabs.co.kr
LabCorp Calabasas Hills, CA	LC/MS/MS ⁺	#070001 Testosterone, Total, Women, Children, and Hypogonadal Males, LC MS/MS	2.50 - 5,000 (250,000 with validated dilution)	8.77 - 840 10.9 - 753 8.77 - 753 8.77 - 941 8.77 - 941 8.77 - 941 9.51 - 941 8.77 - 941 8.77 - 941 8.77 - 941 13.1 - 941 9.63 - 840	Q4 2022 Q3 2022 Q2 2022 Q1 2022 Q4 2021 Q3 2021 Q2 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	72 72 72 80 95 90 88 78 82 82 88 90	Majid Moridani moridam@labcorp.com 336-436-3102 Dr. Andre Valcour ValcouA@labcorp.com (336) 436-3854 Dr. Brett Holmquist holmqub@labcorp.com (818) 867-1362
LabCorp Burlington, NC	LC/MS/MS ⁺	#070001 Testosterone, Total, Women, Children, and Hypogonadal Males, LC MS/MS	2.50 - 5,000 (250,000 with validated dilution)	8.53 - 941 8.77 - 941 8.77 - 941 8.77 - 941 8.77 - 941 8.49 - 941 8.49 - 840	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	90 95 95 92 95 98 98	Majid Moridani moridam@labcorp.com 336-436-3102

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date <i>(active for 1 quarter)</i>	Individual Samples Pass Rate (%)	Participant's Contact Information
LabCorp Spokane, WA	LC/MS/MS ⁺	Total Testosterone	2.5 – 1,000 (250,000 with validated dilution)	10.1 - 840 7.71 - 840 7.71 - 840 7.71 - 736 7.71 - 753 8.77 - 753 9.51 - 753 8.77 - 821 8.77 - 941 8.49 - 941 8.49 - 941 7.71 - 941 7.71 - 915	Q4 2022 Q3 2022 Q2 2022 Q1 2022 Q4 2021 Q3 2021 Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	68 52 48 55 57 65 62 62 70 72 80 88 88	Carissa Schmitz MLS(ASCP)CM Schmic4@LabCrop.com (509) 755-8358

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date <i>(active for 1 quarter)</i>	Individual Samples Pass Rate (%)	Participant's Contact Information
Mayo Clinic Rochester, MN	LC/MS/MS ⁺	Total Testosterone	7 – 2,000	8.53 - 821	Q4 2022	65	Sue Reicks reicks.sue@mayo.edu
				8.53 - 840	Q3 2022	62	
				9.51 - 840	Q2 2022	55	
				9.51 - 941	Q1 2022	70	
				10.1 - 941	Q4 2021	60	
				10.1 - 941	Q3 2021	62	
				10.1 - 941	Q2 2021	62	
				8.77 - 651	Q1 2021	55	
				8.77 - 941	Q4 2020	57	
				8.77 - 941	Q3 2020	60	
				8.77 - 941	Q2 2020	72	
				10.6 - 941	Q1 2020	70	
				9.63 - 915	Q4 2019	72	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Penn State University Hershey Medical Center Hershey, PA	LC/MS/MS ⁺	Total Testosterone in Serum	2 - 2,330	8.53 - 736	Q4 2022	68	Yusheng Zhu, PhD, DABCC, FAACC yzhu@pennstatehealth.psu.edu (717) 531-5123
				8.53 - 736	Q3 2022	57	
				8.53 - 736	Q2 2022	60	
				8.77 - 941	Q1 2022	60	
				7.71 - 941	Q4 2021	65	
				7.71 - 941	Q3 2021	72	
				7.71 - 941	Q2 2021	70	
				7.71 - 753	Q1 2021	68	
				8.77 - 821	Q4 2020	68	
				8.77 - 821	Q3 2020	68	
				8.77 - 821	Q2 2020	75	
				9.63 - 840	Q1 2020	78	
				9.63 - 941	Q4 2019	82	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Quest Diagnostics Nichols Institute of Valencia, Inc. Valencia, CA See Table 2 for AMP status	LC/MS/MS ⁺	Serum Total Testosterone	2 - 2,000 (10,000 with dilution)	7.71 - 680	Q4 2022	85	Amit Ghoshal PhD Amit.K.Ghoshal@QuestDiagnostics.com (661) 799-6204
				7.71 - 680	Q3 2022	80	
				7.71 - 680	Q2 2022	80	
				8.77 - 680	Q1 2022	78	
				8.77 - 769	Q4 2021	72	
				8.77 - 821	Q3 2021	75	
				11.0 - 941	Q2 2021	65	
				8.77 - 941	Q1 2021	62	
				8.77 - 941	Q4 2020	65	
				8.49 - 941	Q3 2020	65	
				8.49 - 821	Q2 2020	72	
				8.49 - 821	Q1 2020	70	
				8.49 - 941	Q4 2019	70	
Roche Diagnostics GmbH Penzberg, Germany	LC/MS/MS ⁺	Total Testosterone in Serum	0.8 – 1,800	8.53 - 840	Q2 2022	80	Rupert Schmid rupert.schmid@roche.com +498856-605256
				8.53 - 821	Q1 2022	68	
				8.53 - 821	Q4 2021	75	
				9.51 - 769	Q3 2021	65	
				10.1 - 769	Q2 2021	70	
				8.77 - 941	Q1 2021	70	
				8.77 - 941	Q4 2020	70	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Siemens Healthcare Diagnostics Newark, DE	Chemiluminescence Immunoassay	Serum Total Testosterone	8 - 1,000	11.0 - 941	Q4 2022	28	Dr. Craig Hixson craig.hixson@siemens.com (302) 631-7540
				11.0 - 941	Q3 2022	33	
				11.0 - 736	Q2 2022	31	
				10.9 - 680	Q1 2022	35	
				10.9 - 680	Q4 2021	31	
				9.51 - 680	Q3 2021	21	
				8.77 - 941	Q4 2020	24	
				8.49 - 941	Q3 2020	30	
				8.49 - 941	Q2 2020	24	
				8.49 - 941	Q1 2020	26	
Siemens Healthcare Diagnostics Tarrytown, NY	Chemiluminescence Immunoassay	ADVIA Centaur® Testosterone II Assay	7.0 – 1,500	8.49 - 915	Q4 2019	32	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477
				10.9 - 941	Q4 2022	20	
				10.9 - 941	Q3 2022	22	
				10.1 - 769	Q2 2022	22	
				10.1 - 840	Q1 2022	22	
				10.1 - 840	Q4 2021	32	
				8.53 - 840	Q3 2021	28	
				10.9 - 840	Q2 2021	35	
				8.77 - 821	Q1 2021	35	
				8.77 - 941	Q4 2020	38	
				8.77 - 941	Q3 2020	38	
				8.77 - 941	Q2 2020	38	
				7.71 - 941	Q1 2020	35	
				7.71 - 840	Q4 2019	32	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Siemens Healthcare Diagnostics Tarrytown, NY	Chemiluminescence Immunoassay	Atellica® Testosterone	7.0 – 1,500	8.53 - 769	Q4 2022	25	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477
				8.53 - 840	Q3 2022	22	
				8.53 - 941	Q2 2022	28	
				8.53 - 941	Q1 2022	26	
				8.53 - 941	Q4 2021	26	
				8.53 - 941	Q3 2021	31	
				10.1 - 736	Q2 2021	21	
				8.77 - 659	Q1 2021	18	
				8.77 - 821	Q4 2020	18	
				8.49 - 821	Q3 2020	15	
				8.49 - 821	Q2 2020	20	
				8.49 - 821	Q1 2020	28	
				8.49 - 941	Q4 2019	32	
Siemens Healthcare Diagnostics Tarrytown, NY	Chemiluminescence Immunoassay	ADVIA Centaur CP	7.0 – 1,500	10.1 - 840	Q4 2022	25	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477
				10.1 - 840	Q3 2022	30	
				10.1 - 769	Q2 2022	31	
				9.51 - 769	Q1 2022	33	
				9.51 - 736	Q4 2021	28	
				10.1 - 840	Q3 2021	35	
				8.53 - 840	Q2 2021	38	
				8.53 - 840	Q1 2021	28	
				8.53 - 941	Q4 2020	35	
				8.49 - 941	Q3 2020	32	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (ng/dL)	Certification Measurement Range (ng/dL)	Certification Date <i>(active for 1 quarter)</i>	Individual Samples Pass Rate (%)	Participant's Contact Information
University of Minnesota (MEBRL) Minneapolis, MN	LC/MS/MS†	Total Testosterone in Serum	2 – 2,000	8.53 - 753 7.71 - 753 7.71 - 753 7.71 - 659 8.49 - 941	Q4 2021 Q3 2021 Q2 2021 Q1 2021 Q2 2020	80 70 60 57 75	Revati Koratkar kora0033@umn.edu 612-624-2959

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

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

Table 2: Accuracy-Based Monitoring Programs (AMP) status of secondary location

Participant	Measurement Principle	Assay Identifier	AMP Active Date <i>(active for 1 quarter)</i>	Participant's Contact Information
Quest Diagnostics Chantilly, VA	LC/MS/MS†	Serum Total Testosterone	Q4 2022 Q3 2022 Q2 2022 Q1 2022 Q4 2021 Q3 2021 Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	William Wu PhD William.W.Wu@QuestDiagnostics.com (703) 802-7210