

CDC Hormone Standardization Program (CDC HoSt)

Certified Total Testosterone Assays

From 2019 Q4 and forward

(UPDATED 07/2021)

CDC HoSt started quarterly certification from November 2019 shipment.

See https://www.cdc.gov/labstandards/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.

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 - 680 7.71 - 941 7.71 - 941 8.77 - 941 9.63 - 941 5.70 - 840	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	85 90 92 72 70 52	Canary Tennison canary.tennison@aruplab.com 801-583-2787 x2893
BioReference Laboratories, an OPKO Health Company Elmwood Park, NJ	LC/MS/MS ⁺	Total Testosterone	1 - 4,000	7.71 - 821 8.49 - 915 8.49 - 915 8.49 - 915	Q3 2020 Q2 2020 Q1 2020 Q4 2019	62 72 68 75	Hashim Othman, Ph.D. hothman@bioreference.com
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)	8.77 - 680 8.77 - 941 8.77 - 941 8.77 - 941 7.71 - 941 5.70 - 915	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	68 68 57 50 55 57	Dr. Shalender Bhasin sbhasin@bwh.harvard.edu (617) 525-9040 Liming Peng Lpeng2@bwh.harvard.edu (617) 525-9048
Clinical Chemistry Branch CDC Atlanta, GA	LC/MS/MS ⁺	Total Testosterone in Serum (1036)	0.57 - 12,800	8.77 - 840 8.77 - 941 8.49 - 941 8.49 - 941 8.49 - 941 8.49 - 915	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	92 95 92 98 98 98	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	7.71 - 840 8.77 - 941 8.77 - 941 8.77 - 941 7.71 - 941 7.71 - 753	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	78 82 78 85 85 80	Cristina Hedin, MS 8211 Scicor Drive Indianapolis, IN 46214 cristina.hedin@covance.com (317) 273-7842
Covance Central Laboratories Services, Inc. Geneva, Switzerland	LC/MS/MS ⁺	Total Testosterone	2.00 - 8,000	8.77 - 821	Q1 2021	75	Gaëlle Gilbert gaëlle.gilbert@covance.com 0041 (0) 58 822 7656

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 - 736 8.77 - 753 8.49 - 821 8.49 - 821 8.49 - 840 8.49 - 840	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	68 78 78 92 92 95	S.A.A. van den Berg s.a.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	8.53 - 736 8.77 - 941 8.77 - 941 3.66 - 941	Q1 2021 Q4 2020 Q2 2020 Q1 2020	50 52 48 70	Dr. Christina Wang wang@lundquist.org (310) 222-2503
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 - 941 8.77 - 941 8.77 - 941 13.1 - 941 9.63 - 840	Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	78 82 82 88 90	Dr. Andre Valcour ValcouA@labcorp.com (336) 436-3854 Dr. Brett Holmquist holmquib@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)	8.77 - 941 8.77 - 941 8.77 - 941 8.77 - 941 8.49 - 941 8.49 - 840	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	95 95 92 95 98 98	Hema Ketha Kethah@labcorp.com 336-436-3102
LabCorp Spokane, WA	LC/MS/MS ⁺	Total Testosterone	2.5 - 1000	8.77 - 821 8.77 - 941 8.49 - 941 8.49 - 941 7.71 - 941 7.71 - 915	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	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 (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Mayo Clinic Rochester, MN	LC/MS/MS ⁺	Total Testosterone	7 - 2000	8.77 - 651 8.77 - 941 8.77 - 941 8.77 - 941 10.6 - 941 9.63 - 915	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	55 57 60 72 70 72	Sue Reicks reicks.sue@mayo.edu
Penn State University Hershey Medical Center Hershey, PA	LC/MS/MS ⁺	Total Testosterone in Serum	2 - 2,330	7.71 - 753 8.77 - 821 8.77 - 821 8.77 - 821 9.63 - 840 9.63 - 941	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	68 68 68 75 78 82	Yusheng Zhu, PhD, DABCC, FAACC yzhu@pennstatehealth.psu.edu (717) 531-5123
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)	8.77 - 941 8.77 - 941 8.49 - 941 8.49 - 821 8.49 - 821 8.49 - 941	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	62 65 65 72 70 70	Amit Ghoshal PhD Amit.K.Ghoshal@QuestDiagnostics.com (661) 799-6204
Roche Diagnostics GmbH Penzberg, Germany	LC/MS/MS ⁺	Total Testosterone in Serum	-	8.77 - 941 8.77 - 941	Q1 2021 Q4 2020	70 70	Rupert Schmid rupert.schmid@roche.com +498856-605256
Siemens Healthcare Diagnostics Newark, DE	Chemiluminescence Immunoassay	Serum Total Testosterone	8 - 1,000	8.77 - 941 8.49 - 941 8.49 - 941 8.49 - 941 8.49 - 915	Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	24 30 24 26 32	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	8.77 - 821 8.77 - 941 8.77 - 941 8.77 - 941 7.71 - 941 7.71 - 840	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	35 38 38 38 35 32	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477

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 - 1500	8.77 - 821 8.49 - 821 8.49 - 821 8.49 - 821 8.49 - 941	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	18 18 15 20 28 32	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477
Siemens Healthcare Diagnostics Tarrytown, NY	Chemiluminescence Immunoassay	ADVIA Centaur CP	7.0 - 1500	8.53 - 840 8.53 - 941 8.49 - 941	Q1 2021 Q4 2020 Q3 2020	28 35 32	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477
University of Minnesota (MEBRL) Minneapolis, MN	LC/MS/MS†	Total Testosterone in Serum	2 – 2000	7.71 - 659 8.49 - 941	Q1 2021 Q2 2020	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 (active for 1 quarter)	Participant's Contact Information
Quest Diagnostics Chantilly, VA	LC/MS/MS†	Serum Total Testosterone	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	William Wu PhD William.W.Wu@QuestDiagnostics.com (703) 802-7210