

# ***CDC Hormone Standardization Program (CDC HoSt)***

## **Certified Total Testosterone Assays**

From 2019 Q4 and forward

(UPDATED 09/2020)

CDC VDSCP started quarterly certification from November 2019 shipment.

See [https://www.cdc.gov/labstandards/pdf/hs/CDC\\_Certified\\_Testosterone\\_Procedures-508.pdf](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 VDSCP 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
<b>ARUP Laboratories</b> Salt Lake City, UT	LC/MS/MS <sup>†</sup>	Total Testosterone in Serum	1.00 - 2,500	8.77 - 941 9.63 - 941 5.70 - 840	Q2 2020 Q1 2020 Q4 2019	72 70 52	Canary Tennison <a href="mailto:canary.tennison@aruplab.com">canary.tennison@aruplab.com</a> 801-583-2787 x2893
<b>BioReference Laboratories, an OPKO Health Company</b> Elmwood Park, NJ	LC/MS/MS <sup>†</sup>	Total Testosterone	1 - 4,000	8.49 - 915 8.49 - 915 8.49 - 915	Q2 2020 Q1 2020 Q4 2019	72 68 75	Hashim Othman, Ph.D. <a href="mailto:hothman@bioreference.com">hothman@bioreference.com</a>
<b>Brigham Research Assay Core (BRAC) Laboratory at Harvard Medical School</b> Boston, MA	LC/MS/MS <sup>†</sup>	Serum Total Testosterone	1.00 - 2,000 (>2,000 with dilution)	8.77 - 941 7.71 - 941 5.70 - 915	Q2 2020 Q1 2020 Q4 2019	50 55 57	Dr. Shalender Bhasin <a href="mailto:sbhasin@bwh.harvard.edu">sbhasin@bwh.harvard.edu</a> (617) 525-9040  Liming Peng <a href="mailto:Lpeng2@bwh.harvard.edu">Lpeng2@bwh.harvard.edu</a> (617) 525-9048
<b>Clinical Chemistry Branch CDC</b> Atlanta, GA	LC/MS/MS <sup>†</sup>	Total Testosterone in Serum (1036)	0.57 - 12,800	8.49 - 941 8.49 - 941 8.49 - 915	Q2 2020 Q1 2020 Q4 2019	98 98 98	Lumi Duke, MS <a href="mailto:LDuke@cdc.gov">LDuke@cdc.gov</a> (770) 488-4126
<b>Covance Central Laboratories Services, Inc.</b> Indianapolis, IN	LC/MS/MS <sup>†</sup>	Serum Total Testosterone	2.00 - 8,000	8.77 - 941 7.71 - 941 7.71 - 753	Q2 2020 Q1 2020 Q4 2019	85 85 80	Cristina Hedin, MS 8211 Scicor Drive Indianapolis, IN 46214 <a href="mailto:cristina.hedin@covance.com">cristina.hedin@covance.com</a> (317) 273-7842
<b>Diagnostic Laboratory for Endocrinology, Erasmus University Medical Center</b> Rotterdam, The Netherlands	LC/MS/MS <sup>†</sup>	Serum Testosterone	2 - 1,093	8.49 - 821 8.49 - 840 8.49 - 840	Q2 2020 Q1 2020 Q4 2019	92 92 95	S.A.A. van den Berg <a href="mailto:s.a.a.vandenberg@erasmusmc.nl">s.a.a.vandenberg@erasmusmc.nl</a> S.S. Panchoe - Ramcharan <a href="mailto:s.panchoe@erasmusmc.nl">s.panchoe@erasmusmc.nl</a>

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
<b>Endocrine and Metabolic Research Laboratory at Los Angeles Biomedical Research Institute</b> Torrance, CA	LC/MS/MS†	TDHT	2.0 - 2,000	8.77 - 941 3.66 - 941	Q2 2020 Q1 2020	48 70	Dr. Christina Wang <a href="mailto:wang@lundquist.org">wang@lundquist.org</a> (310) 222-2503
<b>LabCorp</b> 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 13.1 - 941 9.63 - 840	Q2 2020 Q1 2020 Q4 2019	82 88 90	Dr. Andre Valcour <a href="mailto:ValcouA@labcorp.com">ValcouA@labcorp.com</a> (336) 436-3854 Dr. Brett Holmquist <a href="mailto:holmqub@labcorp.com">holmqub@labcorp.com</a> (818) 867-1362
<b>LabCorp</b> 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 8.49 - 941 8.49 - 840	Q2 2020 Q1 2020 Q4 2019	95 98 98	Hema Ketha <a href="mailto:Kethah@labcorp.com">Kethah@labcorp.com</a> 336-436-3102
<b>LabCorp</b> Spokane, WA	LC/MS/MS†	Total Testosterone	2.5 - 1000	8.49 - 941 7.71 - 941 7.71 - 915	Q2 2020 Q1 2020 Q4 2019	80 88 88	Carissa Schmitz MLS(ASCP)CM <a href="mailto:Schmic4@LabCrop.com">Schmic4@LabCrop.com</a> (509) 755-8358
<b>Mayo Clinic</b> Rochester, MN	LC/MS/MS†	Total Testosterone	7 - 2000	8.77 - 941 10.6 - 941 9.63 - 915	Q2 2020 Q1 2020 Q4 2019	72 70 72	Sue Reicks <a href="mailto:reicks.sue@mayo.edu">reicks.sue@mayo.edu</a>
<b>Penn State University Hershey Medical Center</b> Hershey, PA	LC/MS/MS†	Total Testosterone in Serum	2 - 2,330	8.77 - 821 9.63 - 840 9.63 - 941	Q2 2020 Q1 2020 Q4 2019	75 78 82	Yusheng Zhu, PhD, DABCC, FAACC <a href="mailto:yzhu@pennstatehealth.psu.edu">yzhu@pennstatehealth.psu.edu</a> (717) 531-5123
<b>Quest Diagnostics Nichols Institute of Valencia, Inc.</b> Valencia, CA  See <b>Table 2</b> for AMP status	LC/MS/MS†	Serum Total Testosterone	2 - 2,000 (10,000 with dilution)	8.49 - 821 8.49 - 821 8.49 - 941	Q2 2020 Q1 2020 Q4 2019	72 70 70	Amit Ghoshal PhD <a href="mailto:Amit.K.Ghoshal@QuestDiagnostics.com">Amit.K.Ghoshal@QuestDiagnostics.com</a> (661) 799-6204

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
<b>Siemens Healthcare Diagnostics</b> Newark, DE	Chemiluminescence Immunoassay	Serum Total Testosterone	8 - 1,000	8.49 - 941 8.49 - 941 8.49 - 915	Q2 2020 Q1 2020 Q4 2019	24 26 32	Dr. Craig Hixson <a href="mailto:craig.hixson@siemens.com">craig.hixson@siemens.com</a> (302) 631-7540
<b>Siemens Healthcare Diagnostics</b> Tarrytown, NY	Chemiluminescence Immunoassay	ADVIA Centaur® Testosterone II Assay	7.0 - 1500	8.77 - 941 7.71 - 941 7.71 - 840	Q2 2020 Q1 2020 Q4 2019	38 35 32	Neil Parker <a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a> (914) 524-2477
<b>Siemens Healthcare Diagnostics</b> Tarrytown, NY	Chemiluminescence Immunoassay	Atellica® Testosterone	7.0 - 1500	8.49 - 821 8.49 - 821 8.49 - 941	Q2 2020 Q1 2020 Q4 2019	20 28 32	Neil Parker <a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a> (914) 524-2477
<b>University of Minnesota (MEBRL)</b> Minneapolis, MN	LC/MS/MS†	Total Testosterone in Serum	2 – 2000	8.49 – 941	Q2 2020	75	Revati Koratkar <a href="mailto:kora0033@umn.edu">kora0033@umn.edu</a> 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
<b>Quest Diagnostics</b> Chantilly, VA	LC/MS/MS†	Serum Total Testosterone	Q2 2020 Q1 2020 Q4 2019	William Wu PhD <a href="mailto:William.W.Wu@QuestDiagnostics.com">William.W.Wu@QuestDiagnostics.com</a> (703) 802-7210