

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

## ***Certified Total Testosterone Assays***

From 2019 Q4 and forward

(UPDATED 09/2025)

**CDC HoSt started quarterly certification from November 2019 shipment.**

See <https://www.cdc.gov/clinical-standardization-programs/media/pdfs/2024/04/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 <i>(active for 1 quarter)</i>	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 - 2,000	7.71 - 769	Q2 2025	75	Kayla West <a href="mailto:Kayla.west@aruplab.com">Kayla.west@aruplab.com</a> 801-583-2787 x2893
				7.71 - 736	Q1 2025	68	
				8.53 - 840	Q4 2024	70	
				8.77 - 840	Q3 2024	68	
				8.77 - 840	Q2 2024	72	
				8.77 - 840	Q1 2024	88	
				9.51 - 840	Q4 2023	62	
				9.51 - 840	Q3 2023	57	
				7.71 - 840	Q2 2023	62	
				7.71 - 840	Q1 2023	45	
				7.71 - 753	Q4 2022	68	
				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					

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
<b>BioReference Laboratories, an OPKO Health Company</b> 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. <a href="mailto:hothman@bioreference.com">hothman@bioreference.com</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>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)	8.53 - 941	Q2 2025	65	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
				8.53 - 941	Q1 2025	60	
				8.53 - 941	Q4 2024	75	
				8.53 - 941	Q3 2024	78	
				8.53 - 821	Q2 2024	78	
				8.53 - 821	Q1 2024	85	
				8.53 - 753	Q4 2023	85	
				9.51 - 680	Q3 2023	80	
				9.51 - 840	Q2 2023	70	
				9.51 - 840	Q1 2023	65	
				10.9 - 840	Q4 2022	70	
				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 (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
<b>Clinical Chemistry Branch</b> <b>CDC</b> Atlanta, GA	LC/MS/MS <sup>+</sup>	Total Testosterone in Serum (1036)	0.57 - 12,800	7.71 - 680	Q1 2023	90	Lumi Duke, MS <a href="mailto:LDuke@cdc.gov">LDuke@cdc.gov</a> (770) 488-4126
				7.71 - 680	Q4 2022	90	
				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
<b>Covance Central Laboratories Services, Inc.</b> Indianapolis, IN	LC/MS/MS+	Serum Total Testosterone	2.00 - 8,000	8.84 - 753	Q2 2025	88	Cristina Hedin, MS 8211 Scicor Drive Indianapolis, IN 46214 <a href="mailto:cristina.hedin@covance.com">cristina.hedin@covance.com</a> (317) 273-7842
				8.77 - 753	Q1 2025	90	
				8.77 - 840	Q4 2024	95	
				8.53 - 840	Q3 2024	98	
				8.53 - 840	Q2 2024	98	
				8.53 - 941	Q1 2024	85	
				7.71 - 941	Q4 2023	85	
				7.71 - 941	Q3 2023	80	
				9.51 - 941	Q2 2023	80	
				9.51 - 941	Q1 2023	90	
				9.51 - 941	Q4 2022	87	
				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					

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>Covance Central Laboratories Services, Inc.</b> Geneva, Switzerland	LC/MS/MS+	Total Testosterone	2.00 - 8,000	7.71 - 661	Q2 2025	95	Gaelle Gilbert <a href="mailto:gaelle.gilbert@covance.com">gaelle.gilbert@covance.com</a> 0041 (0) 58 822 7656
				7.71 - 769	Q1 2025	98	
				8.53 - 840	Q4 2024	98	
				10.9 - 840	Q3 2024	98	
				12.0 - 840	Q2 2024	98	
				12.0 - 840	Q1 2024	95	
				12.0 - 821	Q4 2023	90	
				12.0 - 821	Q3 2023	88	
				13.4 - 821	Q2 2023	85	
				12.0 - 821	Q1 2023	88	
				12.0 - 629	Q4 2022	88	
				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
<b>Diagnostic Laboratory for Endocrinology, Erasmus University Medical Center</b>  Rotterdam, The Netherlands	LC/MS/MS+	Serum Testosterone	2 - 1,729	7.71 - 680	Q2 2025	90	S.A.A. van den Berg <a href="mailto:s.a.vandenberg@erasmusmc.nl">s.a.vandenberg@erasmusmc.nl</a> S.S. Panchoe - Ramcharan <a href="mailto:s.panchoe@erasmusmc.nl">s.panchoe@erasmusmc.nl</a>
				7.71 - 769	Q1 2025	90	
				8.53 - 769	Q4 2024	95	
				10.9 - 769	Q3 2024	92	
				8.77 - 769	Q2 2024	92	
				8.77 - 769	Q1 2024	95	
				8.77 - 769	Q4 2023	87	
				8.77 - 769	Q3 2023	87	
				9.51 - 769	Q2 2023	85	
				7.71 - 821	Q1 2023	85	
				7.71 - 821	Q4 2022	90	
				7.71 - 941	Q3 2022	88	
				7.71 - 941	Q2 2022	90	
				8.77 - 941	Q1 2022	92	
				7.71 - 941	Q4 2021	80	
				7.71 - 769	Q3 2021	85	
				7.71 - 769	Q2 2021	70	
				7.71 - 736	Q1 2021	68	
				8.77 - 753	Q4 2020	78	
				8.49 - 821	Q3 2020	78	
8.49 - 821	Q2 2020	92					
8.49 - 840	Q1 2020	92					
8.49 - 840	Q4 2019	95					

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 - 1800	7.71 - 769	Q2 2025	70	Dr. Christina Wang <a href="mailto:wang@lundquist.org">wang@lundquist.org</a> (310) 222-2503
				7.71 - 753	Q1 2025	65	
				8.53 - 736	Q4 2024	62	
				8.53 - 656	Q3 2024	62	
				8.53 - 769	Q2 2024	60	
				8.53 - 769	Q1 2024	60	
				8.77 - 769	Q4 2023	57	
				8.77 - 941	Q3 2023	50	
				9.51 - 941	Q2 2023	55	
				7.71 - 941	A1 2023	50	
				7.71 - 941	Q4 2022	50	
				11.0 - 769	Q1 2022	50	
				8.53 - 753	Q4 2021	52	
				8.53 - 753	Q3 2021	65	
				8.53 - 736	Q2 2021	68	
				8.53 - 736	Q1 2021	50	
8.77 - 941	Q4 2020	52					
8.77 - 941	Q2 2020	48					
3.66 - 941	Q1 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
<b>GC Labs</b> Yongin-si, Gyeonggi-do, Republic of Korea	LC/MS/MS+	Total Testosterone	0.8 – 5059.2	7.71 - 840	Q2 2025	100	<p>Sung-Eun Cho, M.D., Ph.D  <a href="mailto:secho1206!!@gclabs.co.kr">secho1206!!@gclabs.co.kr</a></p> <p>Jung-Sun Han  <a href="mailto:jshan@gclabs.co.kr">jshan@gclabs.co.kr</a></p>
				7.71 - 840	Q1 2025	100	
				8.53 - 840	Q4 2024	100	
				8.53 - 840	Q3 2024	100	
				8.53 - 680	Q2 2024	100	
				8.53 - 753	Q1 2024	100	
				8.77 - 941	Q4 2023	98	
				8.77 - 941	Q3 2023	92	
				8.53 - 941	Q2 2023	92	
				8.53 - 941	Q1 2023	92	
				8.53 - 821	Q4 2022	92	
				8.77 - 941	Q3 2022	95	
				8.53 - 736	Q2 2022	88	

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>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)	7.71 - 753	Q2 2025	88	Majid Moridani <a href="mailto:moridam@labcorp.com">moridam@labcorp.com</a> 336-436-3102  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
				7.71 - 753	Q1 2025	90	
				8.77 - 840	Q4 2024	95	
				8.77 - 840	Q3 2024	92	
				8.53 - 840	Q2 2024	92	
				8.53 - 840	Q1 2024	90	
				7.71 - 736	Q4 2023	85	
				7.71 - 840	Q3 2023	88	
				7.71 - 840	Q2 2023	85	
				7.71 - 840	Q1 2023	80	
				8.77 - 840	Q4 2022	72	
				10.9 - 753	Q3 2022	72	
				8.77 - 753	Q2 2022	72	
				8.77 - 941	Q1 2022	80	
				8.77 - 941	Q4 2021	95	
				8.77 - 941	Q3 2021	90	
				9.51 - 941	Q2 2021	88	
				8.77 - 941	Q4 2020	78	
				8.77 - 941	Q3 2020	82	
				8.77 - 941	Q2 2020	82	
13.1 - 941	Q1 2020	88					
9.63 - 840	Q4 2019	90					

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>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)	8.53 - 941	Q2 2021	90	Majid Moridani <a href="mailto:moridam@labcorp.com">moridam@labcorp.com</a> 336-436-3102
				8.77 - 941	Q1 2021	95	
				8.77 - 941	Q4 2020	95	
				8.77 - 941	Q3 2020	92	
				8.77 - 941	Q2 2020	95	
				8.49 - 941	Q1 2020	98	
				8.49 - 840	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
LabCorp Spokane, WA	LC/MS/MS+	Total Testosterone	2.5 – 1,000 (250,000 with validated dilution)	7.71 - 753	Q2 2025	55	Carissa Schmitz MLS(ASCP)CM <a href="mailto:Schmic4@LabCorp.com">Schmic4@LabCorp.com</a> (509) 755-8358
				7.71 - 769	Q1 2025	55	
				8.53 - 769	Q4 2024	57	
				8.77 - 769	Q3 2024	50	
				8.77 - 769	Q2 2024	55	
				8.77 - 769	Q1 2024	78	
				8.77 - 941	Q4 2023	72	
				9.51 - 941	Q3 2023	82	
				9.51 - 941	Q2 2023	82	
				9.51 - 941	Q1 2023	68	
				10.1 - 840	Q4 2022	68	
				7.71 - 840	Q3 2022	52	
				7.71 - 840	Q2 2022	48	
				7.71 - 736	Q1 2022	55	
				7.71 - 753	Q4 2021	57	
				8.77 - 753	Q3 2021	65	
				9.51 - 753	Q2 2021	62	
				8.77 - 821	Q1 2021	62	
				8.77 - 941	Q4 2020	70	
				8.49 - 941	Q3 2020	72	
8.49 - 941	Q2 2020	80					
7.71 - 941	Q1 2020	88					
7.71 - 915	Q4 2019	88					

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 – 2,000	8.53 - 753	Q2 2025	90	Sue Reicks <a href="mailto:reicks.sue@mayo.edu">reicks.sue@mayo.edu</a>
				8.53 - 753	Q1 2025	95	
				8.53 - 659	Q4 2-24	80	
				8.77 - 821	Q3 2023	60	
				8.53 - 821	Q2 2023	75	
				8.53 - 821	Q1 2023	65	
				8.53 - 821	Q4 2022	65	
				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
<b>Penn State University Hershey Medical Center</b> Hershey, PA	LC/MS/MS <sup>+</sup>	Total Testosterone in Serum	2 - 2,637	7.71 - 840	Q2 2025	72	Yusheng Zhu, PhD, DABCC, FAACC <a href="mailto:yzhu@pennstatehealth.psu.edu">yzhu@pennstatehealth.psu.edu</a> (717) 531-5123
				7.71 - 840	Q1 2025	75	
				8.53 - 840	Q4 2024	75	
				8.53 - 840	Q3 2024	82	
				8.53 - 769	Q2 2024	75	
				8.53 - 736	Q1 2024	72	
				7.71 - 736	Q4 2023	68	
				7.71 - 736	Q3 2023	65	
				7.71 - 736	Q2 2023	65	
				7.71 - 651	Q1 2023	70	
				8.53 - 736	Q4 2022	68	
				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
<b>Quest Diagnostics Nichols Institute of Valencia, Inc.</b> Valencia, CA  See Table 2 for AMP status	LC/MS/MS+	Serum Total Testosterone	2 - 2,000 (10,000 with dilution)	8.53 - 680	Q2 2023	90	Amit Ghoshal PhD <a href="mailto:Amit.K.Ghoshal@QuestDiagnostics.com">Amit.K.Ghoshal@QuestDiagnostics.com</a> (661) 799-6204
				7.71 - 680	Q1 2023	88	
				7.71 - 680	Q4 2022	85	
				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					
<b>Quest Diagnostics</b> San Juan Capistrano, CA	LC/MS/MS+	Serum Total Testosterone	1 - 10000	7.71 - 769	Q2 2025	52	Allan Fraser <a href="mailto:dgxsicqacls@questdiagnostics.com">dgxsicqacls@questdiagnostics.com</a>
				7.71 - 753	Q1 2025	60	
				8.53 - 719	Q4 2024	60	

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>Roche Diagnostics GmbH</b> Penzberg, Germany	LC/MS/MS <sup>+</sup>	Total Testosterone in Serum	0.8 – 1,800	8.77 - 840	Q4 2024	85	Judith Taibon <a href="mailto:judith.taibon@roche.com">judith.taibon@roche.com</a> 0049 8856 60 12941
				8.77 - 840	Q3 2024	80	
				8.77 - 840	Q2 2024	78	
				8.53 - 840	Q1 2024	78	
				8.53 - 753	Q4 2023	85	
				8.53 - 769	Q3 2023	78	
				8.53 - 840	Q2 2022	80	
				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					
<b>Roche Diagnostics GmbH</b> Munich, Germany	LC/MS/MS <sup>+</sup>	Total Testosterone in Serum	1 – 1500	8.53 - 821	Q1 2024	70	Dr. Stefanie Grimm <a href="mailto:Stefanie.grimm.sg2@roche.com">Stefanie.grimm.sg2@roche.com</a> Svenja Treu <a href="mailto:muc.testsidestudy@roche.com">muc.testsidestudy@roche.com</a>
				8.53 - 753	Q4 2023	85	

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	9.51 - 753	Q2 2025	38	Dr. Craig Hixson <a href="mailto:craig.hixson@siemens.com">craig.hixson@siemens.com</a> (302) 631-7540
				10.9 - 769	Q1 2025	35	
				9.51 - 840	Q3 2024	22	
				9.51 - 840	Q2 2024	28	
				9.51 - 840	Q1 2024	22	
				9.51 - 656	Q4 2023	28	
				11.0 - 941	Q4 2022	28	
				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					
8.49 - 915	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	ADVIA Centaur CP	7.0 – 1,500	8.53 - 666	Q2 2025	35	Neil Parker <a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a>
				8.53 - 666	Q1 2025	35	
				8.53 - 840	Q4 2024	38	
				8.77 - 840	Q3 2024	35	
				8.53 - 840	Q2 2024	31	
				8.53 - 769	Q3 2023	23	
				9.51 - 840	Q2 2023	25	
				10.1 - 840	Q1 2023	20	
				10.1 - 840	Q4 2022	25	
				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 (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Siemens Healthcare Diagnostics Tarrytown, NY	Chemiluminescence Immunoassay	ADVIA Centaur® Testosterone II Assay	7.0 – 1,500	8.53 - 769	Q1 2025	30	Neil Parker <a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a>
				8.53 - 821	Q4 2024	38	
				8.77 - 821	Q3 2024	45	
				8.53 - 821	Q2 2024	40	
				8.53 - 821	Q1 2024	38	
				8.53 - 736	Q4 2023	32	
				8.53 - 769	Q3 2023	25	
				10.9 - 941	Q2 2023	25	
				10.9 - 941	Q1 2023	25	
				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	10.9 - 680	Q1 2025	20	Neil Parker <a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a>
				10.9 - 753	Q4 2024	25	
				8.77 - 769	Q3 2024	30	
				8.53 - 821	Q2 2024	32	
				8.53 - 821	Q1 2024	38	
				8.53 - 821	Q4 2023	35	
				8.53 - 821	Q3 2023	30	
				8.53 - 769	Q2 2023	30	
				8.53 - 769	Q1 2023	28	
				8.53 - 769	Q4 2022	25	
				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					

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® CI Testosterone II Assay	7.0 – 1,500	8.53 - 769	Q2 2025	30	Neil Parker <a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a>
				8.53 - 661	Q1 2025	28	
				8.53 - 661	Q4 2024	32	
University of Minnesota (MEBRL) Minneapolis, MN	LC/MS/MS†	Total Testosterone in Serum	2 – 2,000	8.53 - 753	Q4 2021	80	Revati Koratkar <a href="mailto:kora0033@umn.edu">kora0033@umn.edu</a> 612-624-2959
				7.71 - 753	Q3 2021	70	
				7.71 - 753	Q2 2021	60	
				7.71 - 659	Q1 2021	57	
Waters Technologies IDA Business Park, Wexford, Ireland	LC/MS/MS†	Serum Total Testosterone	1– 1930	8.53-821	Q4 2024	92	Danielle Kehoe <a href="mailto:danielle_kehoe@waters.com">danielle_kehoe@waters.com</a>
				7.71-769	Q1 2025	92	
				7.71-661	Q2 2025	90	

† 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
<p><b>Quest Diagnostics</b> Chantilly, VA</p>	<p>LC/MS/MS†</p>	<p>Serum Total Testosterone</p>	<p>Q2 2023 Q1 2023 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</p>	<p>William Wu PhD <a href="mailto:William.W.Wu@QuestDiagnostics.com">William.W.Wu@QuestDiagnostics.com</a> (703) 802-7210</p>