

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

## **Certified Total Testosterone Assays**

From 2019 Q4 and forward

(UPDATED 12/2021)

**CDC HoSt 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 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   |
|--|-----------------------|------------------------------------|-------------------------------------|--|--|--|---|
| <b>ARUP Laboratories</b><br>Salt Lake City, UT   | LC/MS/MS <sup>+</sup> | Total Testosterone in Serum        | 1.00 - 2,500                        | 8.53 - 680<br>7.71 - 680<br>7.71 - 680<br>7.71 - 941<br>7.71 - 941<br>8.77 - 941<br>9.63 - 941<br>5.70 - 840 | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 55<br>75<br>85<br>90<br>92<br>72<br>70<br>52 | Canary Tennison<br><a href="mailto:canary.tennison@aruplab.com">canary.tennison@aruplab.com</a><br>801-583-2787 x2893   |
| <b>BioReference Laboratories, an OPKO Health Company</b><br>Elmwood Park, NJ                 | LC/MS/MS <sup>+</sup> | Total Testosterone                 | 1 - 4,000                           | 7.71 - 821<br>8.49 - 915<br>8.49 - 915<br>8.49 - 915   | Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019   | 62<br>72<br>68<br>75                         | Hashim Othman, Ph.D.<br><a href="mailto:hothman@bioreference.com">hothman@bioreference.com</a>  |
| <b>Brigham Research Assay Core (BRAC) Laboratory at Harvard Medical School</b><br>Boston, MA | LC/MS/MS <sup>+</sup> | Serum Total Testosterone           | 1.00 - 2,000 (>2,000 with dilution) | 7.71 - 941<br>8.77 - 941<br>8.77 - 680<br>8.77 - 941<br>8.77 - 941<br>8.77 - 941<br>7.71 - 941<br>5.70 - 915 | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 72<br>72<br>68<br>68<br>57<br>50<br>55<br>57 | Dr. Shalender Bhasin<br><a href="mailto:sbhasin@bwh.harvard.edu">sbhasin@bwh.harvard.edu</a><br>(617) 525-9040<br><br>Liming Peng<br><a href="mailto:lpeng2@bwh.harvard.edu">lpeng2@bwh.harvard.edu</a><br>(617) 525-9048 |
| <b>Clinical Chemistry Branch CDC</b><br>Atlanta, GA  | LC/MS/MS <sup>+</sup> | Total Testosterone in Serum (1036) | 0.57 - 12,800                       | 11.0 - 840<br>8.77 - 840<br>8.77 - 941<br>8.49 - 941<br>8.49 - 941<br>8.49 - 941<br>8.49 - 915               | Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019            | 90<br>92<br>95<br>92<br>98<br>98<br>98       | Lumi Duke, MS<br><a href="mailto:LDuke@cdc.gov">LDuke@cdc.gov</a><br>(770) 488-4126   |
| <b>Covance Central Laboratories Services, Inc.</b><br>Indianapolis, IN                       | LC/MS/MS <sup>+</sup> | Serum Total Testosterone           | 2.00 - 8,000                        | 7.71 - 840<br>7.71 - 840<br>7.71 - 840<br>8.77 - 941<br>8.77 - 941<br>8.77 - 941<br>7.71 - 941<br>7.71 - 753 | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 88<br>78<br>78<br>82<br>78<br>85<br>85<br>80 | Cristina Hedin, MS<br>8211 Scicor Drive<br>Indianapolis, IN 46214<br><a href="mailto:cristina.hedin@covance.com">cristina.hedin@covance.com</a><br>(317) 273-7842   |

| 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><br>Geneva, Switzerland                                       | LC/MS/MS <sup>+</sup> | Total Testosterone   | 2.00 - 8,000                                      | 12.2 - 769<br>12.2 - 769<br>8.77 - 821   | Q3 2021<br>Q2 2021<br>Q1 2021  | 75<br>70<br>75                               | Gaelle Gilbert<br><a href="mailto:gaelle.gilbert@covance.com">gaelle.gilbert@covance.com</a><br>0041 (0) 58 822 7656   |
| <b>Diagnostic Laboratory for Endocrinology, Erasmus University Medical Center</b><br>Rotterdam, The Netherlands | LC/MS/MS <sup>+</sup> | Serum Testosterone   | 2 - 1,093   | 7.71 - 769<br>7.71 - 769<br>7.71 - 736<br>8.77 - 753<br>8.49 - 821<br>8.49 - 821<br>8.49 - 840<br>8.49 - 840 | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 85<br>70<br>68<br>78<br>78<br>92<br>92<br>95 | S.A.A. van den Berg<br><a href="mailto:s.a.a.vandenberg@erasmusmc.nl">s.a.a.vandenberg@erasmusmc.nl</a><br>S.S. Panchoe - Ramcharan<br><a href="mailto:s.panchoe@erasmusmc.nl">s.panchoe@erasmusmc.nl</a>      |
| <b>Endocrine and Metabolic Research Laboratory at Los Angeles Biomedical Research Institute</b><br>Torrance, CA | LC/MS/MS <sup>+</sup> | TDHT   | 2.0 - 2,000                                       | 8.53 - 753<br>8.53 - 736<br>8.53 - 736<br>8.77 - 941<br>8.77 - 941<br>3.66 - 941                             | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q2 2020<br>Q1 2020                       | 65<br>68<br>50<br>52<br>48<br>70             | Dr. Christina Wang<br><a href="mailto:wang@lundquist.org">wang@lundquist.org</a><br>(310) 222-2503   |
| <b>LabCorp</b><br>Calabasas Hills, CA   | LC/MS/MS <sup>+</sup> | #070001<br>Testosterone, Total, Women, Children, and Hypogonadal Males, LC MS/MS | 2.50 - 5,000<br>(250,000 with validated dilution) | 8.77 - 941<br>9.51 - 941<br>8.77 - 941<br>8.77 - 941<br>8.77 - 941<br>13.1 - 941<br>9.63 - 840               | Q3 2021<br>Q2 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019            | 90<br>88<br>78<br>82<br>82<br>88<br>90       | Dr. Andre Valcour<br><a href="mailto:ValcouA@labcorp.com">ValcouA@labcorp.com</a><br>(336) 436-3854<br>Dr. Brett Holmquist<br><a href="mailto:holmquib@labcorp.com">holmquib@labcorp.com</a><br>(818) 867-1362 |
| <b>LabCorp</b><br>Burlington, NC  | LC/MS/MS <sup>+</sup> | #070001<br>Testosterone, Total, Women, Children, and Hypogonadal Males, LC MS/MS | 2.50 - 5,000<br>(250,000 with validated dilution) | 8.53 - 941<br>8.77 - 941<br>8.77 - 941<br>8.77 - 941<br>8.77 - 941<br>8.49 - 941<br>8.49 - 840               | Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019            | 90<br>95<br>95<br>92<br>95<br>98<br>98       | Hema Ketha<br><a href="mailto:Kethah@labcorp.com">Kethah@labcorp.com</a><br>336-436-3102   |

| 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><br>Spokane, WA   | LC/MS/MS <sup>+</sup> | Total Testosterone          | 2.5 – 1,000                         | 8.77 - 753<br>9.51 - 753<br>8.77 - 821<br>8.77 - 941<br>8.49 - 941<br>8.49 - 941<br>7.71 - 941<br>7.71 - 915 | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 65<br>62<br>62<br>70<br>72<br>80<br>88<br>88 | Carissa Schmitz MLS(ASCP)CM<br><a href="mailto:Schmic4@LabCrop.com">Schmic4@LabCrop.com</a><br>(509) 755-8358                      |
| <b>Mayo Clinic</b><br>Rochester, MN   | LC/MS/MS <sup>+</sup> | Total Testosterone          | 7 – 2,000                           | 10.1 - 941<br>10.1 - 941<br>8.77 - 651<br>8.77 - 941<br>8.77 - 941<br>8.77 - 941<br>10.6 - 941<br>9.63 - 915 | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 62<br>62<br>55<br>57<br>60<br>72<br>70<br>72 | Sue Reicks<br><a href="mailto:reicks.sue@mayo.edu">reicks.sue@mayo.edu</a>   |
| <b>Penn State University Hershey Medical Center</b><br>Hershey, PA  | LC/MS/MS <sup>+</sup> | Total Testosterone in Serum | 2 - 2,330                           | 7.71 - 941<br>7.71 - 941<br>7.71 - 753<br>8.77 - 821<br>8.77 - 821<br>8.77 - 821<br>9.63 - 840<br>9.63 - 941 | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 72<br>70<br>68<br>68<br>68<br>75<br>78<br>82 | Yusheng Zhu, PhD, DABCC, FAACC<br><a href="mailto:yzhu@pennstatehealth.psu.edu">yzhu@pennstatehealth.psu.edu</a><br>(717) 531-5123 |
| <b>Quest Diagnostics Nichols Institute of Valencia, Inc.</b><br>Valencia, CA<br><br>See <b>Table 2</b> for AMP status | LC/MS/MS <sup>+</sup> | Serum Total Testosterone    | 2 - 2,000<br>(10,000 with dilution) | 8.77 - 821<br>11.0 - 941<br>8.77 - 941<br>8.77 - 941<br>8.49 - 941<br>8.49 - 821<br>8.49 - 821<br>8.49 - 941 | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 75<br>65<br>62<br>65<br>65<br>72<br>70<br>70 | Amit Ghoshal PhD<br><a href="mailto:Amit.K.Ghoshal@QuestDiagnostics.com">Amit.K.Ghoshal@QuestDiagnostics.com</a><br>(661) 799-6204 |
| <b>Roche Diagnostics GmbH</b><br>Penzberg, Germany  | LC/MS/MS <sup>+</sup> | Total Testosterone in Serum | 0.8 – 1,800                         | 9.51 - 769<br>10.1 - 769<br>8.77 - 941<br>8.77 - 941   | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020   | 65<br>70<br>70<br>70                         | Rupert Schmid<br><a href="mailto:rupert.schmid@roche.com">rupert.schmid@roche.com</a><br>+498856-605256                            |

| 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><br>Newark, DE       | Chemiluminescence Immunoassay | Serum Total Testosterone             | 8 - 1,000                       | 9.51 - 680<br>8.77 - 941<br>8.49 - 941<br>8.49 - 941<br>8.49 - 941<br>8.49 - 915                             | Q3 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019                       | 21<br>24<br>30<br>24<br>26<br>32             | Dr. Craig Hixson<br><a href="mailto:craig.hixson@siemens.com">craig.hixson@siemens.com</a><br>(302) 631-7540                          |
| <b>Siemens Healthcare Diagnostics</b><br>Tarrytown, NY    | Chemiluminescence Immunoassay | ADVIA Centaur® Testosterone II Assay | 7.0 – 1,500                     | 8.53 - 840<br>10.9 - 840<br>8.77 - 821<br>8.77 - 941<br>8.77 - 941<br>8.77 - 941<br>7.71 - 941<br>7.71 - 840 | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 28<br>35<br>35<br>38<br>38<br>38<br>35<br>32 | Neil Parker<br><a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a><br>(914) 524-2477 |
| <b>Siemens Healthcare Diagnostics</b><br>Tarrytown, NY    | Chemiluminescence Immunoassay | Atellica® Testosterone               | 7.0 – 1,500                     | 8.53 - 941<br>10.1 - 736<br>8.77 - 821<br>8.49 - 821<br>8.49 - 821<br>8.49 - 821<br>8.49 - 941               | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | 31<br>21<br>18<br>18<br>15<br>20<br>28<br>32 | Neil Parker<br><a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a><br>(914) 524-2477 |
| <b>Siemens Healthcare Diagnostics</b><br>Tarrytown, NY    | Chemiluminescence Immunoassay | ADVIA Centaur CP                     | 7.0 – 1,500                     | 10.1 - 840<br>8.53 - 840<br>8.53 - 840<br>8.53 - 941<br>8.49 - 941   | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020                                  | 35<br>38<br>28<br>35<br>32                   | Neil Parker<br><a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a><br>(914) 524-2477 |
| <b>University of Minnesota (MEBRL)</b><br>Minneapolis, MN | LC/MS/MS†                     | Total Testosterone in Serum          | 2 – 2,000                       | 7.71 - 753<br>7.71 - 753<br>7.71 - 659<br>8.49 - 941   | Q3 2021<br>Q2 2021<br>Q1 2021<br>Q2 2020   | 70<br>60<br>57<br>75                         | Revati Koratkar<br><a href="mailto:kora0033@umn.edu">kora0033@umn.edu</a><br>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<br>(active for 1 quarter)                                 | Participant's Contact Information  |
|------------------------------------|-----------------------|-----------------------------|---|--|
| Quest Diagnostics<br>Chantilly, VA | LC/MS/MS†             | Serum Total<br>Testosterone | Q2 2021<br>Q1 2021<br>Q4 2020<br>Q3 2020<br>Q2 2020<br>Q1 2020<br>Q4 2019 | William Wu PhD<br><a href="mailto:William.W.Wu@QuestDiagnostics.com">William.W.Wu@QuestDiagnostics.com</a><br>(703) 802-7210 |