CDC Hormone Standardization Program (CDC HoSt)

Certified Estradiol Assays

From 2019 Q4 and forward

(UPDATED 09/2023)

CDC HoSt Programs started quarterly certification from November 2019 shipment.

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

- The following assays have successfully met the performance criteria of ±12.5% mean bias (for samples >20 pg/mL) and ±2.5 pg/mL absolute bias (for samples ≤20 pg/mL) when compared to the CDC reference measurement procedure for estradiol for 80% of samples.
- It is not the intent of the CDC HoSt Program to certify each lot of reagents. Participants are awarded certificates for successfully meeting bias criteria 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. This information was provided on the website starting June 2019.

Note: The ±12.5% 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.

Table 1: Currently Certified Assays including their certification history

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (pg/mL)	Certification Measurement Range (pg/mL)	Certification Date *(active for 1 quarter)*	Individual Samples Pass Rate (%)	Participant's Contact Information
ARUP Laboratories Salt Lake City, UT	LC/MS/MS†	Estradiol by TMS	2 - 1000	2.70 - 230 2.70 - 230 2.50 - 230 2.55 - 230 2.55 - 230 2.50 - 216 2.70 - 230 2.70 - 230 3.01 - 230 3.05 - 230 2.55 - 230	Q2 2023 Q1 2023 Q4 2022 Q3 2022 Q2 2022 Q1 2022 Q4 2021 Q3 2021 Q2 2021 Q1 2021 Q4 2020	88 85 95 90 90 98 98 100 95 95 92	Kayla West Kayla.west@aruplab.com 801-583-2787 x2893

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (pg/mL)	Certification Measurement Range (pg/mL)	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 Estradiol	1.00 - 500.00 (& higher than 500 pg/mL with dilution)	2.50 - 230 2.50 - 230 2.50 - 230 2.50 - 230 3.01 - 230 2.55 - 230 2.55 - 230 2.55 - 216 2.55 - 216 2.70 - 216 2.55 - 230 2.55 - 230 2.55 - 230 2.55 - 230 3.40 - 268	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	92 92 95 90 90 85 88 92 92 98 98 90 95 92 92	Dr. Shalender Bhasin SBHASIN@PARTNERS.ORG (617)525-9040 Liming Peng Lpeng2@partners.org (617)525-9048
Centre Hospitalier Universitaire de Liège Sart-Tilman, Belgium	LC/MS/MS†	25(OH)D3+25(OH)D2+C3-epimer+24,25(OH)2D in serum and plasma	5 - 1156	9.64 - 230 9.64 - 230 6.21 - 216	Q1 2023 Q4 2022 Q2 2020	84 86 85	Etienne Cavalier etienne.cavalier@chu.ulg.ac.be +3243667692

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (pg/mL)	Certification Measurement Range (pg/mL)	Certification Date *(active for 1 quarter)*	Individual Samples Pass Rate (%)	Participant's Contact Information
Clinical Chemistry Branch **CDC** Atlanta, GA	LC/MS/MS†	Total Estradiol in Serum (1036)	1.72 - 17,100	3.05 - 230	Q1 2023	98	Lumi Duke, MS LDuke@cdc.gov (770)488-4126
				3.05 - 230	Q4 2022	98	
				3.05 - 230	Q3 2022	100	
				3.05 - 230	Q2 2022	98	
				3.05 - 230	Q1 2022	98	
				4.10 - 230	Q4 2021	98	
				3.01 - 230	Q3 2021	98	
				3.01 - 230	Q2 2021	100	
				3.01 - 230	Q1 2021	100	
				1.75 - 230	Q4 2020	100	
				1.75 - 230	Q3 2020	100	
				1.75 - 230	Q2 2020	100	
				1.75 - 230	Q1 2020	98	
				2.55 - 216	Q4 2019	98	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (pg/mL)	Certification Measurement Range (pg/mL)	Certification Date *(active for 1 quarter)*	Individual Samples Pass Rate (%)	Participant's Contact Information
Covance Central Laboratory Services Indianapolis, IN	LC/MS/MS†	Total Estradiol in Serum (E2)	0.50 - 4,000	3.05 - 230 2.55 - 230 2.55 - 230 2.55 - 230 2.55 - 230 2.70 - 230 2.70 - 230 2.50 - 230 2.50 - 230 2.50 - 230 2.50 - 230 2.70 - 230 2.55 - 268 2.55 - 268 2.55 - 268	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	90 92 100 100 100 100 100 100 100 100 100 100 100 100 90	Cristina Hedin, MS Covance Central Laboratory Services Cristina.Hedin@covance.com 317-273-7842
LabCorp Burlington, NC	LC/MS/MS†	Estradiol in Serum	2.5 - 5000	4.07 - 230 2.55 - 230 2.55 - 230 2.55 - 230 2.55 - 230	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020	90 90 90 88 85	Majid Moridani moridam@labcorp.com 336-436-3102

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (pg/mL)	Certification Measurement Range (pg/mL)	Certification Date *(active for 1 quarter)*	Individual Samples Pass Rate (%)	Participant's Contact Information
LabCorp Calabasas Hills, CA	LC/MS/MS†	#500108 Estradiol, LC/MS (Endocrine Sciences)	1 - 500 (1 to 5,000 with validated dilution)	2.50 - 230 2.50 - 230 2.50 - 230 2.70 - 230 2.70 - 230 2.70 - 230 2.55 - 230 2.55 - 230 2.55 - 230 2.55 - 230 2.55 - 230 2.55 - 230 2.55 - 230 2.55 - 268 3.40 - 268	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	92 95 90 88 85 88 95 98 100 98 98 90 88 90 90	Majid Moridani moridam@labcorp.com 336-436-3102 Dr. Brett Holmquist holmqub@labcorp.com (818) 867-1362 Dr. Kelly Chun chunk@labcorp.com (818) 867-1358

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (pg/mL)	Certification Measurement Range (pg/mL)	Certification Date *(active for 1 quarter)*	Individual Samples Pass Rate (%)	Participant's Contact Information
LabCorp Spokane, WA	LC/MS/MS†	ESTRADIOL (LCMSMS)	2.5 - 625 (2.5 - 5000 with validated dilution)	3.95 - 230	Q2 2023	92	Carissa Schmitz MLS(ASCP)CM Schmic4@LabCrop.com (509) 755-8358
				3.95 - 230	Q1 2023	90	
				3.95 - 230	Q4 2022	88	
				4.70 - 230	Q3 2022	85	
				4.07 - 230	Q2 2022	87	
				4.07 - 230	Q1 2022	92	
				4.07 - 230	Q4 2021	90	
				3.95 - 230	Q3 2021	88	
				3.95 - 230	Q2 2021	85	
				3.95 - 230	Q1 2021	85	
				3.95 - 230	Q4 2020	90	
				4.97 - 230	Q3 2020	88	
				6.21 - 230	Q2 2020	95	
				6.21 - 230	Q1 2020	98	
				5.90 - 216	Q4 2019	88	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (pg/mL)	Certification Measurement Range (pg/mL)	Certification Date *(active for 1 quarter)*	Individual Samples Pass Rate (%)	Participant's Contact Information
Mayo Clinic Rochester, MN	LC/MS/MS†	Estradiol	10 - 600	11.7 - 230	Q2 2023	95	Sue Reicks reicks.sue@mayo.edu
				11.7 - 230	Q1 2023	95	
				11.7 - 230	Q4 2022	95	
				11.7 - 230	Q3 2022	92	
				11.7 - 230	Q2 2022	95	
				11.7 - 230	Q1 2022	100	
				11.4 - 230	Q4 2021	100	
				11.4 - 230	Q3 2021	100	
				11.4 - 230	Q2 2021	100	
				11.4 - 230	Q1 2021	100	
				11.7 - 230	Q4 2020	100	
				11.8 - 230	Q3 2020	95	
				17.1 - 230	Q2 2020	95	
				17.1 - 216	Q1 2020	95	
				16.6 - 230	Q4 2019	92	

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (pg/mL)	Certification Measurement Range (pg/mL)	Certification Date *(active for 1 quarter)*	Individual Samples Pass Rate (%)	Participant's Contact Information
Roche Diagnostics GmbH Penzberg, Germany	LC/MS/MS†	Total Estradiol in Serum and Plasma	5 - 5000	9.64 - 230 9.64 - 230 11.4 - 230 9.64 - 230 9.64 - 230 9.34 - 216 9.34 - 230 9.34 - 230 9.34 - 230 9.64 - 230 9.64 - 230	Q2 2023 Q1 2023 Q4 2022 Q3 2022 Q2 2022 Q1 2022 Q4 2021 Q3 2021 Q2 2021 Q1 2021 Q4 2020	100 100 100 100 92 92 92 92 95 92 92	Judith Taibon judith.taibon@roche.com 0049 8856 60 12941

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