

CDC Hormone Standardization Program (CDC HoSt)

Certified Estradiol Assays

From 2019 Q4 and forward

(UPDATED 12/2020)

CDC HoSt Programs started quarterly certification from November 2019 shipment.

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

- The following assays have successfully met the performance criteria of $\pm 12.5\%$ 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.

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
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)	2.55 - 230 2.55 - 230 2.55 - 230 3.40 - 268	Q3 2020 Q2 2020 Q1 2020 Q4 2019	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	6.21 - 216	Q2 2020	85	Etienne Cavalier etienne.cavalier@chu.ulg.ac.be +3243667692
Clinical Chemistry Branch CDC Atlanta, GA	LC/MS/MS ⁺	Total Estradiol in Serum (1036)	1.72 - 17,100	1.75 - 230 1.75 - 230 1.75 - 230 2.55 - 216	Q3 2020 Q2 2020 Q1 2020 Q4 2019	100 100 98 98	Lumi Duke, MS LDuke@cdc.gov (770)488-4126
Covance Central Laboratory Services Indianapolis, IN	LC/MS/MS ⁺	Total Estradiol in Serum (E2)	0.50 - 4,000	2.70 - 230 2.55 - 268 2.55 - 268 2.55 - 268	Q3 2020 Q2 2020 Q1 2020 Q4 2019	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	2.55 - 230 2.55 - 230	Q3 2020 Q2 2020	88 85	Hema Ketha Kethah@LabCorp.com 336-436-3102
LabCorp Calabasas Hills, CA	LC/MS/MS ⁺	#500108 Estradiol, LC/MS (Endocrine Sciences)	1 - 500 (1 to 5,000 with validated dilution)	2.55 - 230 2.55 - 230 2.55 - 268 3.40 - 268	Q3 2020 Q2 2020 Q1 2020 Q4 2019	90 88 90 90	Dr. Brett Holmquist holmqub@labcorp.com (818) 867-1362 Dr. Kelly Chun chunk@labcorp.com (818) 867-1358
LabCorp Spokane, WA	LC/MS/MS ⁺	ESTRADIOL (LCMSMS)	2.5 - 625 (2.5 - 5000 with validated dilution)	4.97 - 230 6.21 - 230 6.21 - 230 5.90 - 216	Q3 2020 Q2 2020 Q1 2020 Q4 2019	88 95 98 88	Carissa Schmitz MLS(ASCP)CM Schmic4@LabCrop.com (509) 755-8358

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	11.8 - 230 17.1 - 230 17.1 - 216 16.6 - 230	Q3 2020 Q2 2020 Q1 2020 Q4 2019	95 95 95 92	Sue Reicks reicks.sue@mayo.edu

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