

CDC Hormone Standardization Program (CDC HoSt)

Certified Estradiol Assays

From 2019 Q4 and forward

(UPDATED 03/2020)

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.
- CDC HoSt Program certifies the performance of assays within the concentration range of 1.5-210 pg/mL for estradiol.
- 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 certification date. It is the responsibility of the participant to ensure that the results of their method 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, method identifier, measurement range, certification date, individual samples pass rate, and contact information.

“Method identifier” is an internal code used by the participant to represent the method used for certification.

“Measurement range” is the assays’ reported analytical measurement range (AMR) and is not the certification range.

“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	Method Identifier	Estradiol 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)	2019 Q4	92	Dr. Shalender Bhasin SBHASIN@PARTNERS.ORG (617)525-9040 Liming Peng Lpeng2@partners.org (617)525-9048
Clinical Chemistry Branch CDC Atlanta, GA	LC/MS/MS†	Total Estradiol in Serum (1036)	1.72-17,100	2019 Q4	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	2019 Q4	90	Cristina Hedin, MS Covance Central Laboratory Services Cristina.Hedin@covance.com 317-273-7842
LabCorp Calabasas Hills, CA	LC/MS/MS†	#500108 Estradiol, LC/MS (Endocrine Sciences)	1–500 (1 to 5,000 with validated dilution)	2019 Q4	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)	2019 Q4	88	Carissa Schmitz MLS(ASCP)CM Schmic4@LabCrop.com (509) 755-8358
Mayo Clinic Rochester, MN	LC/MS/MS†	Estradiol	10-600	2019 Q4	92	Sue Reicks reicks.sue@mayo.edu

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