CDC Hormone Standardization Program (CDC HoSt)

Certified Estradiol Procedures

(UPDATED 09/2018)

- The following laboratories 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.
- CDC HoSt Program certifies the performance of participants 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. Laboratories 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 year. During that year, it is the responsibility of the participant to ensure that the results of their method remain consistent throughout the year, 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.

There are two tables. Table 1 is the list of assays that are currently certified with the CDC HoSt Program. Table 2 is the list of assays that have been certified previously but are not currently certified. Participants are listed in alphabetical order.

Each table includes information about certified/previously certified participants, including name, measurement principle, method identifier, measurement range, certification date, and contact information.

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

"Measurement range" is the participants' 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.

Table 1: Currently Certified Assays including their certification history (for previously certified participants with no current certificate, see Table 2)

Participant	Measurement Principle	Method Identifier	Estradiol Measurement Range (pg/mL)	Certification Date *(active for 1 year)*	Participant's Contact Information
BioReference Laboratories, an OPKO Health Company	LC/MS/MS†	Estradiol in serum (E2)	5.0–2,000	Aug 2018 Aug 2017	Hashim Othman, Ph.D hothman@bioreference.com
Brigham Research Assay Core (BRAC) Laboratory at Harvard Medical School	LC/MS/MS†	Serum Estradiol	1.00–500.00 (& higher than 500 pg/mL with dilution)	Feb 2018 Feb 2017 Feb 2016	Dr. Shalender Bhasin SBHASIN@PARTNERS.ORG (617)525-9040 Liming Peng Lpeng2@partners.org (617)525-9048
Clinical Chemistry Branch CDC	LC/MS/MS†	Total Estradiol in Serum (1033)	2.99–1,400 (2.99–3,000 with dilution)	Nov 2017 Nov 2016 Nov 2015	Lumi Duke, MS LDuke@cdc.gov (770)488-4126 Hui Zhou, PhD HZhou2@cdc.gov (770)488-4861
Covance Central Laboratory Services	LC/MS/MS†	Total Estradiol in Serum (E2)	0.50–4,000	May 2018 May 2017 May 2016 May 2015	Cristina Hedin, MS Covance Central Laboratory Services Cristina.Hedin@covance.com 317-273-7842
Craft Technologies, Inc.	LC/MS/MS†	Serum Estradiol and Estrogen Metabolites CTI Code# BF-69	1.0–1,000	May 2017	Neal Craft, PhD mncraft@crafttechnologies.com Matt Fleshman, PhD mfleshman@crafttechnologies.com 252-206-7071

Participant	Measurement Principle	Method Identifier	Estradiol Measurement Range (pg/mL)	Certification Date *(active for 1 year)*	Participant's Contact Information
LabCorp	LC/MS/MS†	#500108 Estradiol, LC/MS (Endocrine Sciences)	1–500 (1 to 5,000 with validated dilution)	Aug 2018 Aug 2017 Aug 2016 Aug 2015	Dr. Walt Chandler Chandld@labcorp.com (818)867-1370 Dr. Brett Holmquist holmqub@labcorp.com (818) 867-1362 Dr. Kelly Chun chunk@labcorp.com (818) 867-1358

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

Table 2: Previously certified assays with no current certification

Participant	**Measurement Principle**	**Method Identifier**	**Estradiol Measurement Range** (pg/mL)	**Certification Date** *(active for 1 year)*	**Participant's Contact information**
Endoceutics	LC/MS/MS†	Total Serum Estradiol Multi-Analyte Method	1–50 (1-500 with validated dilution)	Aug 2016	Renaud Gonthier, B.Sc. renaud.gonthier@endoceutics.com Jean-Nicolas Simard, M.Sc. jean-nicolas.simard@endoceutics.com
TriCore Reference Labs	LC/MS/MS†	HPLC-MS/MS	2–5,000 pg/mL	Feb 2016	Larry Crockett, MT(ASCP) TriCore Reference Laboratories Technical Supervisor, Esoteric Analytical Chemistry 1001 Woodward Place NE, Albuquerque, NM 87102 (505) 938-8095 (Office) or (505) 938-8968 (Lab) larry.crockett@tricore.org
Pathology Associates Medical Laboratory, LLC	LC/MS/MS†	ESTRADIOL (LCMSMS)	5.0–625 (5-1,250 with validated dilution)	May 2017 May 2016	Carissa Schmitz MLS(ASCP)CM cschmitz@paml.com (509) 755-8358
ZRT Laboratory	LC/MS/MS†	Serum Total Estradiol – Multi-Analyte Method	5.0–1,000	May 2017	David T. Zava, Ph.D. dzava@zrtlab.com David W. Kimball, M.S. dwkimball@zrtlab.com

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