

CDC Vitamin D Standardization-Certification Program (CDC VDSCP) ***Certified Total 25-hydroxyvitamin D Procedures***

(UPDATED 09/2020)

- The following laboratories have successfully met the performance criterion of $\pm 5.0\%$ mean bias when compared to the CDC reference measurement procedure and an overall imprecision of $<10\%$. **Only data for total 25-hydroxyvitamin D was used for certification.**
- CDC VDSCP certifies the performance of participants within the concentration range of 22-275nmol/L for total 25-hydroxyvitamin D.
- It is not the intent of the CDC VDSCP to certify each lot of reagents. Laboratories are awarded certificates for successfully meeting bias and imprecision criteria using specific methods that consist of different reagent and calibrator lots.
- Analytical performance in the CDC VDSCP 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 VDSCP. 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, pass rate of individual samples, 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.

“Individual samples pass rate” is the percentage of individual samples out of the 40 provided that met certification criteria of $\pm 5\%$ bias. This information was provided starting February 2017.

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	Total 25OHD Measurement Range (nmol/L)	Certification Date (active for 1 year)	Individual Samples Pass Rate (%)	Participant's Contact Information
Abbott GmbH Longford, Ireland	Chemiluminescence Immunoassay	ALINITY 25-OH Vitamin D (List Number 08P45)	8.5-385.5	Aug 2019	28	Ronan O'Neill Ronan.O'Neill@abbott.com +353 (0)43-33-31008
Abbott GmbH Longford, Ireland	Chemiluminescence Immunoassay	ARCHITECT 25-OH Vitamin D (List Number 5P02)	8.5-389.8	Aug 2019 Aug 2018 Aug 2017 May 2017 Feb 2016	42 28 38 38 N/A	Ronan O'Neill Ronan.O'Neill@abbott.com +353 (0)43-33-31008
Affimedix, Inc. Hayward, CA	Sandwich ELISA	MicrO - D™ 25-OH Vitamin D (total)	4.2-375	Feb 2019	30	Kevin Wang Kwang@affimedix.com
ARUP Laboratories, Inc. Salt Lake City, UT	LC/MS/MS†	25-Hydroxyvitamin D2 and D3 by Tandem Mass Spectrometry, Serum	2.5-249.6	Aug 2019 Aug 2018 Aug 2017	65 53 58	Canary Tennison canary.tennison@aruplab.com 801-583-2787 x2893
Boditech Med Inc. Gangwon-do, South Korea	Fluorescence ImmunoAssay	Boditech Med Ichroma Vitamin D 25(OH)D2/D3	20-175	Nov 2019	22	Jiusu Kim Kjs3@boditech.co.kr 82-33-243-1400
CCR Laboratory University of Maryland Clinical Pathology Baltimore, MD	LC/MS/MS†	Total 25 OH-Vitamin D 10 – 400 nmol/mL	10-400	Aug 2019 Aug 2018 Aug 2017 Aug 2016	57 65 68 N/A	Dr. Show-Hong Duh sduh@umm.edu (410) 328-5705
Chemux Bioscience Hayward, CA (now operated as PerkinElmer Health Sciences Inc.)	ELISA	25 OH Vitamin D ELISA 80min	4.18-375	Feb 2019	22	Shawn You chemuxbio@gmail.com 650-872-1800
Covance Central Laboratory Services, Inc. Indianapolis, IN	LC/MS/MS†	Total 25 Hydroxy-Vitamin D2/D3	1.25-1,996.80	Aug 2019 Aug 2018 Aug 2017 Aug 2016 Aug 2015 Aug 2014	88 70 65 N/A N/A N/A	Cristina Hedin cristina.hedin@covance.com (317) 273-7842

Participant	Measurement Principle	Method Identifier	Total 25OHD Measurement Range (nmol/L)	Certification Date (active for 1 year)	Individual Samples Pass Rate (%)	Participant's Contact Information
Department of Clinical Chemistry, University of Liege, CHU Sart-Tilman Liege, Belgium	LC/MS/MS†	25(OH)D3+25(OH)D2+C3-epimer+24,25(OH)2D	4.12-624	Feb 2019	65	Prof. Etienne Cavalier etienne.cavalier@chu.ulg.ac.be +32 4 3668822
DiaSorin Stillwater, MN	Chemiluminescence Immunoassay	LIAISON® 25 OH Vitamin D TOTAL Assay	10–375	Nov 2019 Nov 2018 Nov 2017 Nov 2016 Nov 2015 Nov 2014	32 22 38 N/A N/A N/A	Kym Pieper kym.pieper@diasorin.com (651) 351-5861 Cole Gilman cole.gilman@diasorin.com (651) 351-5933
DIASource Immunoassays Louvain-la-Neuve, Belgium	ELISA	25OH Vitamin D ELISA 90'	15 - 338	Nov 2018	32	Nicolas Heurreux Nicolas.Heurreux@diasource.be +32 10849940
Diazyme Laboratories, Inc. Poway, CA	Immunoturbidimetric Assay	Diazyme EZ Vitamin D Total Assay	18.9-369	Feb 2019	26	Dr. Chao Dou chao.dou@diazyme.com 858-455-4763
Douglas Hanly Moir Pathology Sydney, Australia	LC/MS/MS†	Serum 25 hydroxyvitamin D2 and D3 by LC/MS/MS	3.90 - 600	May 2018	55	Andy Liu aliu@dhm.com.au (61) 2 98555275
Endocrine Sciences Laboratory, LabCorp Calabasas Hills, CA	LC/MS/MS†	Test Code 500510 (Total)	2.4–625	Feb 2019 Feb 2018 Feb 2017 Feb 2016 Feb 2015 Feb 2014	62 50 55 N/A N/A N/A	Dr. Brett Holmquist Holmqub@labcorp.com (818)867-1362
Eurofins – Biomnis Ivry-Sur-Seine, France	LC/MS/MS†	MassChrom® 25-OH-Vitamin D3/D2 and 3-épi-25-OH Vitamin D3/D2 in Serum/Plasma	5.0-600	Aug 2019 Aug 2018	45 65	Isabelle Petit isabellepetiti@eurofins.com +33(0)149591672
Euroimmun Germany	Immunoassay	EUROIMMUN ELISA (EQ 6411-9601)	10-300	Aug 2019	22	Victor Herbst v.herbst@euroimmun.de 49451585523133

Participant	Measurement Principle	Method Identifier	Total 25OHD Measurement Range (nmol/L)	Certification Date (active for 1 year)	Individual Samples Pass Rate (%)	Participant's Contact Information
Fujirebio Inc. Tokyo, Japan	Chemiluminescence Enzyme Immunoassay	Lumipulse® G 25-OH Vitamin D	10–375	Aug 2019 Nov 2017 Nov 2016 Nov 2015	68 35 N/A N/A	Satoshi Saito Satoshi.Saito@miraca.com +81-3-6279-0809
Heartland Assays Ames, IA	LC/MS/MS†	25(OH)D2/D3 via LC/MS/MS	3.75- 500	Feb 2019 Feb 2018	75 68	Drew Makowski Drew.makowski@heartlandassays.com or John Rathmacher John.rathmacher@heartlandassays.com
Immunodiagnostic Systems (IDS) Tyne and Wear, GB	ELISA	25-Hydroxy Vitamin D EIA	16.3 - 250	Feb 2019 Feb 2018 Feb 2017 Feb 2014	38 25 25 N/A	Heather Pham Heather.pham@idsplc.com
Immunodiagnostic Systems (IDS) Tyne and Wear, GB	CLIA	IDS 25 VitD ⁵	10 - 275	Feb 2019 Feb 2018 Feb 2017 Feb 2014	42 40 45 N/A	Heather Pham Heather.pham@idsplc.com
Metabolomics Australia, Centre for Microscopy, Characterisation and Analysis, University of Western Australia Perth, Australia	LC/MS/MS†	Serum 25(OH)D3, Epi-25(OH)D3, 25(OH)D2	2–200	Aug 2018 Aug 2017 Aug 2016 Aug 2015 Aug 2014	43 35 N/A N/A N/A	Dr. Michael W Clarke michael.clarke@uwa.edu.au
Mayo Medical Laboratories Rochester, MN	LC/MS/MS†	Serum 25 hydroxyvitamin D2 and D3	15-740	Mar 2019 Feb 2014	60 N/A	Larry Dodge Dodge.larry@mayo.edu (507)-538-0400 Eric Bro Bro.eric@mayo.edu (507)266-4348
Monobind, Inc. Lake Forest, CA	ELISA	25-OH Vitamin D Total (Vit D-Direct)	6.5-375	Feb 2019	25	Tony Shatola tonyshatola@monobind.com

Participant	Measurement Principle	Method Identifier	Total 25OHD Measurement Range (nmol/L)	Certification Date (active for 1 year)	Individual Samples Pass Rate (%)	Participant's Contact Information
Nutrition Research Division Health Canada Ottawa, Canada	LC-MS/MS ⁺	Serum Total 25OHD, 25OHD3, 25OHD2 and 3-epi-25OHD3	2.5–275	Aug 2019 Aug 2018 Aug 2017 Aug 2016	60 73 77 N/A	Dr. Stephen Brooks steve.brooks@hc-sc.gc.ca (603) 957-0932 Kurtis Sarafin kurtis.sarafin@hc-sc.gc.ca (613) 957-0921
Nutritional Biomarkers Branch CDC Atlanta, GA	LC-MS/MS ⁺	#4027 routine method for serum 25OHD3, 25OHD2, C3-epimer-25OHD3	4–430	May 2019 May 2018 May 2017 May 2016	78 75 85 N/A	Rosemary Schleicher, PhD RSchleicher@cdc.gov (770) 488-4424
Ortho Clinical Diagnostics Pencoed, Wales, UK	CIA	Vitros	20-375	Aug 2019	22	Aled Yates aled.yates@orthoclinicaldiagnostics.com (+44) 1656 778501
Quest Diagnostics Nichols Institute of Valencia, Inc Valencia, California	LC/MS/MS ⁺	Total 25-HydroxyvitaminD (Vitamin D2/Vitamin D3)	10–1,280	Feb 2019 Feb 2018 Feb 2017 Nov 2015 Nov 2014	60 65 73 N/A N/A	Amit Ghoshal PhD Amit.K.Ghoshal@QuestDiagnostics.com Quest Diagnostics Nichols Institute Valencia, Inc. (661) 799-6204
RD-Ratio Diagnostics Frankfurt, Germany	Immunoassay	E-VTD-K50 *now marketed as VD455B (Infinitium Biotech) by Calibiotech	6.25-375	Feb 2019	8	RD-Ratio Diagnostics Arash Nikaeen arash5333@gmail.com 1-818-805-49
Roche Diagnostics GmbH Penzberg, DE	ECL binding assay	Elecsys Vitamin D total II	7.5–250	Nov 2018 Nov 2017 Feb 2015	23 43 N/A	Christian Vogl christian.vogl.cv1@roche.com +49 8856 60 19758
SCIEX Diagnostics Framingham, MA	LC/MS/MS ⁺	Total 25-HydroxyvitaminD (Vitamin D2/Vitamin D3)	10-800	May 2019 May 2018 May 2016 May 2015	78 55 N/A N/A	Theresa Irvine Theresa.Irvine@sciex.com 508-383-7409
SCIEX Diagnostics Framingham, MA	LC/MS/MS ⁺	Total 25-HydroxyvitaminD (Vitamin D2/Vitamin D3) II	10-800	May 2019 May 2018	57 90	Theresa Irvine Theresa.Irvine@sciex.com 508-383-7409

Participant	Measurement Principle	Method Identifier	Total 25OHD Measurement Range (nmol/L)	Certification Date (active for 1 year)	Individual Samples Pass Rate (%)	Participant's Contact Information
Siemens Healthcare Diagnostics Tarrytown, NY	Chemiluminescence Immunoassay	ADVIA Centaur® Vitamin D Total assay	10.5–375	Feb 2019 Feb 2018 Feb 2017 Feb 2016 Feb 2015 Feb 2014	18 28 25 N/A N/A N/A	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477
Siemens Healthcare Diagnostics Tarrytown, NY	Chemiluminescence Immunoassay	Atellica® IM Vitamin D Total assay	10.5–375	Nov 2019 Nov 2018	25 28	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477
Siemens Healthcare Diagnostics Newark, DE	Chemiluminescence Immunoassay	Dimension®ExL™ Vitamin D Total assay	12.5–375	Aug 2019 Aug 2018 Aug 2017	42 40 23	Dr. Tie Wei tie.q.wei@siemens-healthineers.com (302)631-6929 Jie Li jie.l.li@siemens-healthineers.com (302)631-7708
SNIBE Shenzhen, China	Chemiluminescence Immunoassay	Maglumi 25-OH Vitamin D	7.5-375	Nov 2019 Nov 2018	30 35	Jinyun Yuan jinyun.yuan@snibe.cn
Thermo Fisher Scientific Finland	LC/MS/MS†	Thermo Scientific™ Cascadion™ SM 25-Hydroxy Vitamin D	3.4-264	Nov 2019	72	Sirpa Riistama-Laari Sirpa.riistama-laari@thermofisher.com +358 103292215
University of Minnesota, Molecular Epidemiology and Biomarker Research Laboratory (MEBRL) Minneapolis, MN	LC/MS/MS†	25-Hydroxy Vitamin D2 and D3	5.3–1,240	Nov 2019 Nov 2018 Nov 2017 Nov 2016 Nov 2015 Nov 2014	42 65 78 N/A N/A N/A	Dr. Myron Gross gross001@umn.edu (612) 624-5417
Waters Wexford, Ireland	LC-MS/MS†	Total Vitamin D (25(OH)D3 25(OH)D2) in plasma* and serum	10–375	Aug 2018 Aug 2017 Aug 2016	38 50 N/A	Norma Breen norma_breen@waters.com 00353 (0) 53 9160514

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

N/A: not available. Note: Pass Rates are provided as of February 2017

* Certification is only provided for serum. No assessment was performed in plasma.

Table 2: Previously certified assays with no current certification

Participant	Measurement Principle	Method Identifier	Total 25OHD Measurement Range (nmol/L)	Certification Date (active for 1 year)	Individual Samples Pass Rate (%)	Participant's Contact Information
Abbott Laboratories	Chemiluminescence Immunoassay	ARCHITECT 25-OH Vitamin D (List Number 3L52)	32.5–240.0	Aug 2016 May 2015	N/A N/A	Karen Gignac karen.gignac@abbott.com (224) 667-4649
BioReference Laboratories, an OPKO Hkorkh Company	LC/MS/MS†	25-Hydroxy Vitamin D2/D3, in serum/plasma*	10 – 188	Aug 2017	68	Hashim Othman, Ph.D. hothman@bioreference.com
Chromsystems Instruments & Chemicals GmbH	LC-MS/MS†	MassChrom® 25-OH-Vitamin D3/D2 in Serum/Plasma*	1.50–624	May 2017 May 2016 May 2015	85 N/A N/A	Dr. Ralf Fischer fischer@chromsystems.de +49 89 189 30 0
Cork Centre for Vitamin D and Nutrition Research Cork, Ireland	LC/MS/MS†	Total serum 25OHD	3.84-491	Feb 2018 Feb 2017 Feb 2016 Feb 2015 Feb 2014	68 85 N/A N/A N/A	Prof. Kevin Cashman k.cashman@ucc.ie +353 21 4901317
Department of Clinical Chemistry, University of Liege, CHU Sart-Tilman Liege, Belgium	LC/MS/MS†	Serum Total Vitamin D	5–625	May 2018 May 2017 May 2016 May 2015 May 2014	63 78 N/A N/A N/A	Prof. Etienne Cavalier etienne.cavalier@chu.ulg.ac.be +32 4 3668822
Douglass Hanly Moir Pathology	LC/MS/MS†	Serum 25 hydroxyvitamin D2 and D3	4–600	May 2017 May 2016 May 2015 May 2014	63 N/A N/A N/A	Dr. Grahame Caldwell gcaldwell@dhm.com.au +61 298555380 Andy Liu aliu@dhm.com.au +61 298555275
Epitope Diagnostics, Inc. San Diego, CA	Enzymatic (EIA)	Total 25-OH Vitamin D _{2/3}	14.8-375	Nov 2018	23	Stefanie Lenart-Dallezotte slenart@epitopediagnostics.com
Immunodiagnostic Systems (IDS)	Chemiluminescence Immunoassay	IDS-iSYS 25-Hydroxy Vitamin D ^s	18–313	Feb 2016 Feb 2015 Feb 2014	N/A N/A N/A	Heather Pham heather.pham@idsplc.com +447408846732
InSource Diagnostics Monrovia, CA	LC/MS/MS†	Sensieva™ 25OH Vitamin D2/D3 (20uL Serum/Plasma* Method)	6.06–492.00	Aug 2018 Aug 2017	53 43	Michael Rummel michaelr@insourcedx.com 1-(626)-386-5277 Justin Wotring justinw@insourcedx.com 1-626-386-5277

Pathology Associates Medical Laboratory, LLC	LC/MS/MS†	VITAMIN D2 D3, 25-HYDROXY BY LC/MS/MS	10.0-300	Feb 2014	N/A	Dr. Carmen Wiley Carmen.wiley@paml.com (509)755-8554
Roche Diagnostics GmbH	LC/MS/MS†	25-Hydroxyvitamin D and Vitamin D metabolites		Feb 2015	N/A	Stephan Pongratz stephan.pongratz@roche.com +49 8856 60 6383
Seoul Clinical Laboratory(SCL), Korea	LC-MS/MS†	Serum total 25-hydroxyvitamin D (25-hydroxyvitamin D2, 25-hydroxyvitamin D3), 3-epi-25-hydroxyvitamin D3		May 2015	N/A	Dr. Young-Jin Kim(Medical Director) yjkim@scllab.co.kr +82-2-330-2011 Sanghoo Lee, PhD sprout30@scllab.co.kr +82-70-7115-8697
Tosoh Corporation	Enzyme Immunoassay	ST AIA-PACK 25-OH Vitamin D	10-300	Feb 2017	30	Dr. Sachi-yuki Hasegawa sachi-yuki-hasegawa-de@tosoh.co.jp

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

N/A: not available. Note: Pass Rates are provided as of February 2017