

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

(UPDATED 03/2019)

- 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
<b>Abbott GmbH</b> Longford, Ireland	Chemiluminescence Immunoassay	ARCHITECT 25-OH Vitamin D (List Number 5P02)	8.5–389.8	Aug 2018 Aug 2017 May 2017 Feb 2016	28 38 38 N/A	Ronan O'Neill <a href="mailto:Ronan.O'Neill@abbott.com">Ronan.O'Neill@abbott.com</a> +353 (0)43-33-31008
<b>Affimedix, Inc.</b> Hayward, CA	Sandwich ELISA	MicrO - D™ 25-OH Vitamin D (total)	4.2-375	Feb 2019	30	Kevin Wang <a href="mailto:Kwang@affimedix.com">Kwang@affimedix.com</a>
<b>ARUP Laboratories, Inc.</b> Salt Lake City, UT	LC/MS/MS+	25-Hydroxyvitamin D2 and D3 by Tandem Mass Spectrometry, Serum	2.5–249.6	Aug 2018 Aug 2017	53 58	Canary Tennison <a href="mailto:canary.tennison@aruplab.com">canary.tennison@aruplab.com</a> 801-583-2787 x2893
<b>CCR Laboratory University of Maryland Clinical Pathology</b> Baltimore, MD	LC/MS/MS+	Total 25 OH-Vitamin D 10 – 400 nmol/mL	10–400	Aug 2018 Aug 2017 Aug 2016	65 68 N/A	Dr. Show-Hong Duh <a href="mailto:sduh@umm.edu">sduh@umm.edu</a> (410) 328-5705
<b>Chemux Bioscience</b> Hayward, CA	ELISA	25 OH Vitamin D ELISA 80min	4.18-375	Feb 2019	22	Shawn You <a href="mailto:chemuxbio@gmail.com">chemuxbio@gmail.com</a> 650-872-1800
<b>Covance Central Laboratory Services, Inc.</b> Indianapolis, IN	LC/MS/MS+	Total 25 Hydroxy-Vitamin D2/D3	1.25–1,996.80	Aug 2018 Aug 2017 Aug 2016 Aug 2015 Aug 2014	70 65 N/A N/A N/A	Cristina Hedin <a href="mailto:cristina.hedin@covance.com">cristina.hedin@covance.com</a> (317) 273-7842
<b>Department of Clinical Chemistry, University of Liege, CHU Sart-Tilman</b> 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 <a href="mailto:etienne.cavalier@chu.ulg.ac.be">etienne.cavalier@chu.ulg.ac.be</a> +32 4 3668822

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
<b>DiaSorin</b> Stillwater, MN	Chemiluminescence Immunoassay	LIAISON® 25 OH Vitamin D TOTAL Assay	10–375	Nov 2018 Nov 2017 Nov 2016 Nov 2015 Nov 2014	22 38 N/A N/A N/A	Kym Pieper <a href="mailto:kym.pieper@diasorin.com">kym.pieper@diasorin.com</a> (651) 351-5861  Cole Gilman <a href="mailto:cole.gilman@diasorin.com">cole.gilman@diasorin.com</a> (651) 351-5933
<b>DIASource Immunoassays</b> Louvain-la-Neuve, Belgium	ELISA	25OH Vitamin D ELISA 90'	15 - 338	Nov 2018	32	Nicolas Heurreux <a href="mailto:Nicolas.Heurreux@diasource.be">Nicolas.Heurreux@diasource.be</a> +32 10849940
<b>Diazyme Laboratories, Inc.</b> Poway, CA	Immunoturbidimetric Assay	Diazyme EZ Vitamin D Total Assay	18.9-369	Feb 2019	26	Dr. Chao Dou <a href="mailto:chao.dou@diazyme.com">chao.dou@diazyme.com</a> 858-455-4763
<b>Endocrine Sciences Laboratory, LabCorp</b> Calabasas Hills, CA	LC/MS/MS <sup>+</sup>	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 <a href="mailto:Holmqub@labcorp.com">Holmqub@labcorp.com</a> or Dr. Walt Chandler <a href="mailto:Chandld@labcorp.com">Chandld@labcorp.com</a> (800) 444-9111
<b>Epitope Diagnostics, Inc.</b> San Diego, CA	Enzymatic (EIA)	Total 25-OH Vitamin D <sub>2/3</sub>	14.8-375	Nov 2018	23	Stefanie Lenart-Dallezotte <a href="mailto:slenart@epitopediagnostics.com">slenart@epitopediagnostics.com</a>
<b>Eurofins – Biomnis</b> Ivry-Sur-Seine, France	LC/MS/MS <sup>+</sup>	MassChrom® 25-OH-Vitamin D3/D2 and 3-épi-25-OH Vitamin D3/D2 in Serum/Plasma	5.0-600	Aug 2018	65	Isabelle Petit <a href="mailto:isabellepetiti@eurofins.com">isabellepetiti@eurofins.com</a> +33(0)149591672
<b>Heartland Assays</b> Ames, IA	LC/MS/MS <sup>+</sup>	25(OH)D2/D3 via LC/MS/MS	3.75- 500	Feb 2019 Feb 2018	75 68	Drew Makowski <a href="mailto:Drew.makowski@heartlandassays.com">Drew.makowski@heartlandassays.com</a> or John Rathmacher <a href="mailto:John.rathmacher@heartlandassays.com">John.rathmacher@heartlandassays.com</a>
<b>Immunodiagnostic Systems (IDS)</b> 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 <a href="mailto:Heather.pham@idsplc.com">Heather.pham@idsplc.com</a>

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
<b>Immunodiagnostic Systems (IDS)</b> Tyne and Wear, GB	CLIA	IDS 25 VitD <sup>S</sup>	10 - 275	Feb 2019 Feb 2018 Feb 2017 Feb 2014	42 40 45 N/A	Heather Pham <a href="mailto:Heather.pham@idsplc.com">Heather.pham@idsplc.com</a>
<b>InSource Diagnostics</b> Monrovia, CA	LC/MS/MS <sup>+</sup>	Sensieva™ 25OH Vitamin D2/D3 (20uL Serum/Plasma* Method)	6.06–492.00	Aug 2018 Aug 2017	53 43	Michael Rummel <a href="mailto:michaels@insourcedx.com">michaels@insourcedx.com</a> 1-(626)-386-5277  Justin Wotring <a href="mailto:justinw@insourcedx.com">justinw@insourcedx.com</a> 1-626-386-5277
<b>Metabolomics Australia, Centre for Microscopy, Characterisation and Analysis, University of Western Australia</b> Perth, Australia	LC/MS/MS <sup>+</sup>	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 <a href="mailto:michael.clarke@uwa.edu.au">michael.clarke@uwa.edu.au</a>
<b>Mayo Medical Laboratories</b> Rochester, MN	LC/MS/MS <sup>+</sup>	Serum 25 hydroxyvitamin D2 and D3	15-740	Mar 2019 Feb 2014	60 N/A	Larry Dodge <a href="mailto:Dodge.larry@mayo.edu">Dodge.larry@mayo.edu</a> (507)-538-0400 Eric Bro <a href="mailto:Bro.eric@mayo.edu">Bro.eric@mayo.edu</a> (507)266-4348
<b>Monobind, Inc.</b> Lake Forest, CA	ELISA	25-OH Vitamin D Total (Vit D-Direct)	6.5-375	Feb 2019	25	Tony Shatola <a href="mailto:tonyshatola@monobind.com">tonyshatola@monobind.com</a>
<b>Nutrition Research Division Health Canada</b> Ottawa, Canada	LC-MS/MS <sup>+</sup>	Serum Total 25OHD, 25OHD3, 25OHD2 and 3-epi-25OHD3	2.5–275	Aug 2018 Aug 2017 Aug 2016	73 77 N/A	Dr. Stephen Brooks <a href="mailto:steve.brooks@hc-sc.gc.ca">steve.brooks@hc-sc.gc.ca</a> (603) 957-0932  Kurtis Sarafin <a href="mailto:kurtis.sarafin@hc-sc.gc.ca">kurtis.sarafin@hc-sc.gc.ca</a> (613) 957-0921

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
<b>Nutritional Biomarkers Branch CDC</b> Atlanta, GA	LC-MS/MS <sup>+</sup>	#4027 routine method for serum 25OHD3, 25OHD2, C3-epimer-25OHD3	4–430	May 2018 May 2017 May 2016	75 85 N/A	Rosemary Schleicher, PhD <a href="mailto:RSchleicher@cdc.gov">RSchleicher@cdc.gov</a> (770) 488-4424
<b>Quest Diagnostics Nichols Institute of Valencia, Inc</b> Valencia, California	LC/MS/MS <sup>+</sup>	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 <a href="mailto:Amit.K.Ghoshal@QuestDiagnostics.com">Amit.K.Ghoshal@QuestDiagnostics.com</a> Quest Diagnostics Nichols Institute Valencia, Inc. (661) 799-6204
<b>RD-Ratio Diagnostics</b> 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 <a href="mailto:arash5333@gmail.com">arash5333@gmail.com</a> 1-818-805-49
<b>Roche Diagnostics GmbH</b> 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 <a href="mailto:christian.vogl.cv1@roche.com">christian.vogl.cv1@roche.com</a> +49 8856 60 19758
<b>SCIEX Diagnostics</b> Framingham, MA	LC/MS/MS <sup>+</sup>	Total 25-HydroxyvitaminD (Vitamin D2/Vitamin D3)	10-800	May 2018 May 2016 May 2015	55 N/A N/A	Theresa Irvine <a href="mailto:Theresa.Irvine@sciex.com">Theresa.Irvine@sciex.com</a> 508-383-7409
<b>SCIEX Diagnostics</b> Framingham, MA	LC/MS/MS <sup>+</sup>	Total 25-HydroxyvitaminD (Vitamin D2/Vitamin D3) II	10-800	May 2018	90	Theresa Irvine <a href="mailto:Theresa.Irvine@sciex.com">Theresa.Irvine@sciex.com</a> 508-383-7409
<b>Siemens Healthcare Diagnostics</b> 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 <a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a> (914) 524-2477
<b>Siemens Healthcare Diagnostics</b> Tarrytown, NY	Chemiluminescence Immunoassay	Atellica® IM Vitamin D Total assay	10.5–375	Nov 2018	28	Neil Parker <a href="mailto:neil.np.parker@siemens-healthineers.com">neil.np.parker@siemens-healthineers.com</a> (914) 524-2477

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
<b>Siemens Healthcare Diagnostics</b> Newark, DE	Chemiluminescence Immunoassay	Dimension®ExL™ Vitamin D Total assay	12.5–375	Aug 2018 Aug 2017	40 23	Dr. Tie Wei <a href="mailto:tie.q.wei@siemens-healthineers.com">tie.q.wei@siemens-healthineers.com</a> (302)631-6929  Jie Li <a href="mailto:jie.l.li@siemens-healthineers.com">jie.l.li@siemens-healthineers.com</a> (302)631-7708
<b>SNIBE</b> Shenzhen, China	Chemiluminescence Immunoassay	Maglumi 25-OH Vitamin D	7.5-375	Nov 2018	35	Jinyun Yuan <a href="mailto:jinyun.yuan@snibe.cn">jinyun.yuan@snibe.cn</a>
<b>University of Minnesota, Molecular Epidemiology and Biomarker Research Laboratory (MEBRL)</b> Minneapolis, MN	LC/MS/MS†	25-Hydroxy Vitamin D2 and D3	5.3–1,240	Nov 2018 Nov 2017 Nov 2016 Nov 2015 Nov 2014	65 78 N/A N/A N/A	Dr. Myron Gross <a href="mailto:gross001@umn.edu">gross001@umn.edu</a> (612) 624-5417
<b>Waters</b> 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 <a href="mailto:norma_breen@waters.com">norma_breen@waters.com</a> 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 <a href="mailto:karen.gignac@abbott.com">karen.gignac@abbott.com</a> (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. <a href="mailto:hothman@bioreference.com">hothman@bioreference.com</a>
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 <a href="mailto:fischer@chromsystems.de">fischer@chromsystems.de</a> +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 <a href="mailto:k.cashman@ucc.ie">k.cashman@ucc.ie</a> +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 <a href="mailto:etienne.cavalier@chu.ulg.ac.be">etienne.cavalier@chu.ulg.ac.be</a> +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 <a href="mailto:gcaldwell@dhm.com.au">gcaldwell@dhm.com.au</a> +61 298555380  Andy Liu <a href="mailto:aliu@dhm.com.au">aliu@dhm.com.au</a> +61 298555275
Fujirebio Inc. Tokyo, Japan	Chemiluminescence Enzyme Immunoassay	Lumipulse® G 25-OH Vitamin D	10–375	Nov 2017 Nov 2016 Nov 2015	35 N/A N/A	Satoshi Saito <a href="mailto:Satoshi.Saito@miraca.com">Satoshi.Saito@miraca.com</a> +81-3-6279-0809
Immunodiagnostic Systems (IDS)	Chemiluminescence Immunoassay	IDS-iSYS 25-Hydroxy Vitamin D <sup>S</sup>	18–313	Feb 2016 Feb 2015 Feb 2014	N/A N/A N/A	Heather Pham <a href="mailto:heather.pham@idsplc.com">heather.pham@idsplc.com</a> +447408846732
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 <a href="mailto:Carmen.wiley@paml.com">Carmen.wiley@paml.com</a> (509)755-8554

<b>Roche Diagnostics GmbH</b>	LC/MS/MS†	25-Hydroxyvitamin D and Vitamin D metabolites		Feb 2015	N/A	Stephan Pongratz <a href="mailto:stephan.pongratz@roche.com">stephan.pongratz@roche.com</a> +49 8856 60 6383
<b>Seoul Clinical Laboratory(SCL), Korea</b>	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) <a href="mailto:yjkim@scllab.co.kr">yjkim@scllab.co.kr</a> +82-2-330-2011  Sanghoo Lee, PhD <a href="mailto:sprout30@scllab.co.kr">sprout30@scllab.co.kr</a> +82-70-7115-8697
<b>Tosoh Corporation</b>	Enzyme Immunoassay	ST AIA-PACK 25-OH Vitamin D	10-300	Feb 2017	30	Dr. SachiYuki Hasegawa <a href="mailto:sachiYuki-hasegawa-de@tosoh.co.jp">sachiYuki-hasegawa-de@tosoh.co.jp</a>

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

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