

CDC Vitamin D Standardization-Certification Program (CDC VDSCP)

Certified Total 25-hydroxyvitamin D Assays

From 2019 Q4 and forward

(UPDATED 10/2021)

CDC VDSCP started quarterly certification from November 2019 shipment.

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

- The following assays 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.**
- It is not the intent of the CDC VDSCP to certify each lot of reagents. Participants 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 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, 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 assay’s reported analytical measurement range (AMR) and is not the certification range.

“Certification Measurement Range” is the concentration range the of the samples used for VDSCP 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 certification criteria of $\pm 5\%$ bias. This information was provided starting February 2017.

Table 1: Currently Certified Assays

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (nmol/L)	Certification Measurement Range (nmol/L)	Certification Date (active for 1 quarter)	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	17.4 - 149 16.7 - 149 13.1 - 183 13.1 - 183	Q2 2021 Q1 2021 Q1 2020 Q4 2019	45 42 25 32	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	16.1 - 123 13.1 - 136 13.1 - 149 12.1 - 220 12.1 - 220 12.1 - 220 12.1 - 220	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	40 38 38 35 28 28 35	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	16.1 - 175	Q4 2019	35	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	16.7 - 135 16.1 - 135 16.1 - 149 16.1 - 149 16.1 - 149 18.1 - 183 19.7 - 183	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	65 62 65 78 65 65 60	Canary Tennison canary.tennison@aruplab.com 801-583-2787 x2893
AUTOBIO DIAGNOSTICS CO., LTD. Zhengzhou, China	Chemiluminescence Immunoassay	AutoLumo 25-OH Vitamin D Total Assay	11.25 - 375	13.1 - 140	Q2 2020	26	Zhang Yujiao zhangyujiao@autobio.com.cn 86-371-66785303
Boditech Med Inc. South Korea	Fluorescence Immunoassay	Boditech Med Ichroma Vitamin D 25(OH)D2/D3	20 - 175	22.6 - 123 22.6 - 183 22.0 - 183 12.1 - 183 12.1 - 183 12.1 - 183 12.1 - 183	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	42 38 38 36 28 25 22	Jieun Lee lje@boditech.co.kr 82-70-4264-7575
Boditech Med Inc. South Korea	Fluorescence Immunoassay	Boditech Med AFIAS Vitamin D 25(OH)D2/D3	20 - 175	28.5 - 140 12.1 - 140 12.1 - 135 12.1 - 140	Q2 2021 Q1 2021 Q4 2020 Q3 2020	38 31 31 24	Jieun Lee lje@boditech.co.kr 82-70-4264-7575

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (nmol/L)	Certification Measurement Range (nmol/L)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
CCR Laboratory University of Maryland Clinical Pathology Baltimore, MD	LC/MS/MS ⁺	Total 25 OH-Vitamin D 10 – 400 nmol/mL	10 - 400	17.4 - 140 16.7 - 183 13.1 - 183 13.1 - 183 13.1 - 149 13.1 - 136	Q2 2021 Q1 2021 Q3 2020 Q2 2020 Q1 2020 Q4 2019	50 50 38 35 42 52	Dr. Show-Hong Duh sduh@umm.edu (410) 328-5705
PerkinElmer Health Sciences, Inc Hayward, CA	ELISA	25 OH Vitamin D ELISA 80min	4.18 - 375	17.4 - 198	Q4 2019	28	Shawn You Shaofang.you@perkinelmer.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	16.1 - 135 12.1 - 183 12.1 - 183 12.1 - 183 12.1 - 183 16.1 - 140 18.1 - 140	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	75 72 62 78 82 82 90	Cristina Hedin cristina.hedin@covance.com (317) 273-7842
Centre Hospitalier Universitaire de Liège Sart-Tilman, Belgium	LC/MS/MS ⁺	25(OH)D3+25(OH)D2+C3-epimer+24,25(OH)2D	3.7 - 624	21.5 - 128 12.1 - 136 12.1 - 149 12.1 - 149 12.1 - 198 18.1 - 198 18.1 - 198	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	85 92 92 85 75 62 57	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	13.1 - 183 13.1 - 183 13.1 - 183 13.1 - 138 16.7 - 220 17.4 - 220 17.4 - 220	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	22 12 10 10 12 15 28	Cole Gilman cole.gilman@diasorin.com (651) 351-5933
Diazyme Laboratories, Inc. Poway, CA	Immunoturbidimetric Assay	Diazyme EZ Vitamin D Total Assay	18.9 - 369	21.5 - 140 16.7 - 140 16.7 - 149 18.1 - 149 19.7 - 136	Q2 2021 Q1 2021 Q2 2020 Q1 2020 Q4 2019	14 11 19 21 18	Dr. Chao Dou chao.dou@diazyme.com 858-455-4763

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (nmol/L)	Certification Measurement Range (nmol/L)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Douglass Hanly Moir Pathology Sydney, Australia	LC/MS/MS ⁺	25-Hydroxyvitamin D2 and D3 by Tandem Mass Spectrometry, Serum	3.90 - 600	16.7 - 140 13.1 - 183 12.1 - 183	Q2 2021 Q1 2021 Q4 2020	55 55 68	Andy Liu aliu@dhm.com.au +61298555275
Endocrine Sciences Laboratory, LabCorp Calabasas Hills, CA	LC/MS/MS ⁺	Test Code 500510 (Total)	2.4 - 625	13.1 - 140 13.1 - 149 13.1 - 149 10.4 - 149 10.4 - 175 10.4 - 175 10.4 - 183	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	72 68 62 57 65 72 70	Dr. Brett Holmquist Holmqub@labcorp.com (818)867-1362
Fujirebio INC. Tokyo, Japan	Chemiluminescence Enzyme Immunoassay	Lumipulse® G 25-OH Vitamin D	10 - 375	16.1 - 183	Q1 2020	45	Satoshi Saito satoshi.kojima@miraca.com +81-42-645-4742
Heartland Assays Ames, IA	LC/MS/MS ⁺	25(OH)D2/D3 via LC/MS/MS	3.75 - 500	17.4 - 132 16.7 - 136 12.1 - 136 12.1 - 136 12.1 - 183 12.1 - 183 13.1 - 183	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	67 65 57 65 75 65 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	16.7 - 134 16.1 - 220 16.1 - 220 16.1 - 220 16.1 - 220 10.4 - 183 10.4 - 183	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	23 29 35 24 29 24 18	Heather Pham Heather.pham@idsplc.com
Immunodiagnostic Systems (IDS) Tyne and Wear, GB	CLIA	IDS 25 VitD ^S	10 - 275	12.1 - 135 16.1 - 136 16.1 - 136 12.1 - 138 10.4 - 183 10.4 - 183	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q1 2020 Q4 2019	40 45 38 33 24 26	Heather Pham Heather.pham@idsplc.com

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (nmol/L)	Certification Measurement Range (nmol/L)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Mayo Medical Laboratories Rochester, MN	LC/MS/MS ⁺	Serum 25 hydroxyvitamin D2 and D3	15 - 740	17.4 - 135 18.1 - 135 16.1 - 149 10.4 - 183 10.4 - 183 10.4 - 183 10.4 - 183	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	50 52 55 62 62 67 62	Larry Dodge Dodge.larry@mayo.edu (507)-538-0400 Eric Bro Bro.eric@mayo.edu (507)266-4348
Nutrition Research Division Health Canada Ottawa, Canada	LC-MS/MS ⁺	Serum Total 25OHD, 25OHD3, 25OHD2 and 3-epi-25OHD3	2.5 - 275	13.1 - 183 13.1 - 220 13.1 - 220 13.1 - 220 16.1 - 220 16.7 - 140 19.7 - 140	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	80 72 62 50 40 45 45	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	17.4 - 140 13.1 - 140 13.1 - 140 13.1 - 140 13.1 - 140 19.7 - 140 19.7 - 183	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	80 72 80 78 70 65 70	Rosemary Schleicher, PhD RSchleicher@cdc.gov (770) 488-4424
Ortho Clinical Diagnostics Pencoed, Wales, UK	CIA	Vitros	20 - 375	36.4 - 123 27.5 - 134 22.6 - 136 10.4 - 135 10.4 - 140 19.7 - 220	Q2 2021 Q1 2021 Q4 2020 Q2 2020 Q1 2020 Q4 2019	20 15 15 15 18 22	Aled Yates aled.yates@orthoclinicaldiagnostics.com (+44) 1656 778397
Penn State University, Hershey Medical Center, Dept. of Pathology and Laboratory Medicine Hershey, PA	LC/MS/MS ⁺	25OHD2 and 25OHD3 (39D0657304)	9.98 - 399	16.7 - 147	Q4 2019	62	Yusheng Zhu, PhD, DABCC, FAACC yzhu@pennstatehealth.psu.edu 717-731-5123

Participant	Measurement Principle	Assay Identifier	Assay Measurement Range (nmol/L)	Certification Measurement Range (nmol/L)	Certification Date (active for 1 quarter)	Individual Samples Pass Rate (%)	Participant's Contact Information
Quest Diagnostics Nichols Institute of Valencia, Inc Valencia, California	LC/MS/MS+	Total 25-Hydroxyvitamin D (Vitamin D2/Vitamin D3)	10 - 1,280	12.1 - 123 12.1 - 220 16.7 - 220 16.7 - 220 18.1 - 149 18.1 - 140	Q2 2021 Q1 2021 Q3 2020 Q2 2020 Q1 2020 Q4 2019	42 50 55 65 62 62	Amit Ghoshal PhD Amit.K.Ghoshal@QuestDiagnostics.com Quest Diagnostics Nichols Institute Valencia, Inc. (661) 799-6204
Roche Diagnostics GmbH Penzberg, DE	ECL binding assay	Elecsys Vitamin D total II	7.5 - 250	22.0 - 183 16.7 - 134 13.1 - 136 13.1 - 198 13.1 - 198 13.1 - 198	Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	42 40 42 38 45 45	Christian Vogl christian.vogl.cv1@roche.com +49 8856 60 19758
Roche Diagnostics GmbH Penzberg, DE	ECL binding assay	Elecsys Vitamin D total III	7.5 - 300	12.1 - 149 12.1 - 149	Q2 2021 Q4 2020	15 25	Christian Vogl christian.vogl.cv1@roche.com +49 8856 60 19758
Roche Diagnostics GmbH Penzberg, DE	LC/MS/MS+	25-Hydroxyvitamin D3 and 25-Hydroxyvitamin D2 in serum	D3: 3.75 - 450 D2: 3.64 - 437	16.1 - 134 16.1 - 134	Q2 2021 Q1 2021	78 65	Kerstin Kandler Kerstin.Kandler@roche.com 0049 8856 60 14048
SCIEX Diagnostics Framingham, MA	LC/MS/MS+	Total 25-Hydroxyvitamin D (Vitamin D2/Vitamin D3)	10 - 800	12.1 - 183 19.7 - 183	Q1 2020 Q4 2019	55 52	Theresa Irvine Theresa.Irvine@sciex.com 508-383-7409
Siemens Healthcare Diagnostics Tarrytown, NY	Chemiluminescence Immunoassay	ADVIA Centaur® Vitamin D Total assay	10.5 - 375	13.1 - 135 13.1 - 149 13.1 - 149 13.1 - 149 16.1 - 149 16.1 - 147 17.4 - 183	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	18 18 18 20 15 15 22	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	12.1 - 132 12.1 - 132 12.1 - 132 12.1 - 134 12.1 - 220 16.7 - 220 19.7 - 220	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	18 28 31 32 38 35 30	Neil Parker neil.np.parker@siemens-healthineers.com (914) 524-2477

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Siemens Healthcare Diagnostics Glasgow, DE	Chemiluminescence Immunoassay	Dimension®ExL™ Vitamin D Total assay	12.5 - 375	18.1 - 140 16.7 - 140 12.1 - 140 12.1 - 175 10.4 - 183 10.4 - 183	Q2 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	50 38 38 35 38 32	Dr. Tie Wei tie.g.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	22.0 - 230	Q4 2019	28	Jinyun Yuan jinyun.yuan@snibe.cn
Thermo Fisher Scientific Vantaa, Finland	LC/MS/MS†	Thermo Scientific™ Cascadion™ SM 25-Hydroxy Vitamin D	8.24 - 649.3	18.1 - 149 18.1 - 149 13.1 - 135 13.1 - 147 13.1 - 147 13.1 - 220 16.1 - 220	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	80 80 75 78 75 75 80	Sirpa Riistama-Laari Sirpa.riistama-laari@thermofisher.com +358 103292215
Tosoh Corporation Tokyo, Japan	Enzyme Immunoassay	ST AIA-PACK 25-OH Vitamin D	10 - 375	12.1 - 128 12.1 - 149 16.7 - 149 16.7 - 183 16.7 - 198 19.7 - 198 19.7 - 198	Q2 2021 Q1 2021 Q4 2020 Q3 2020 Q2 2020 Q1 2020 Q4 2019	22 20 20 18 12 20 28	Dr. Sachiyuki Hasegawa sachiyuki-hasegawa-de@tosoh.co.jp Hisao Tsukamoto hisao-tsukamoto-rn@tosoh.co.jp +81-467-76-5384
University Hospital – Biochemistry Laboratory Grenoble, France	LC/MS/MS†	LC/MS/MS† assay 2D LC METHODE	4 - 360	13.1 - 183	Q1 2020	72	Anne Sophie Gauchez ASGauchez@chu-grenoble.fr SGazzah@chu-grenoble.fr
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	16.1 - 149 13.1 - 136 12.1 - 140 12.1 - 183	Q2 2021 Q1 2021 Q2 2020 Q4 2019	60 55 42 45	Dr. Myron Gross gross001@umn.edu (612) 624-5417
Waters Technologies Wexford, Ireland	LC/MS/MS†	Total 25-Hydroxyvitamin D (Vitamin D2/Vitamin D3)	20 - 750	22.0 - 140 13.1 - 140 13.1 - 140 13.1 - 140	Q2 2021 Q1 2021 Q4 2020 Q3 2020	65 60 60 55	Norma Breen Norma.Breen@waters.com 00353 (0)53-9160514

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

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