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References

1. Freeman J, Wilson K. Vitamin D: Progress toward Standardization. *Clinical Laboratory News*. 2013 Aug 1 [cited 2017 Jun]. Available from: <https://www.aacc.org/publications/cln/articles/2013/august/vitamin-d-standardization#ref>
2. CDC Vitamin D Standardization-Certification Program (VDSCP)—Total 25hydroxy Vitamin D Certified Procedures; 2017 Mar [cited 2017 Jun]. Available from: https://www.cdc.gov/labstandards/pdf/hs/CDC_Certified_Vitamin_D_Procedures.pdf



FAQ

CDC Vitamin D Standardization-Certification Program

Frequently Asked Questions

Siemens Healthineers Headquarters

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthineers

Local Contact Information

Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005, USA
Phone: +1-888-826-9702
siemens.com/healthineers

Why is Vitamin D Standardization important?

Using the same patient specimen, vitamin D assays from different commercial sources and platforms can produce inconsistent results—results that can be large enough to impact patient care, changing classifications from sufficient to deficient levels. Standardizing vitamin D assays is therefore, essential.

There are precedents for programs like the VDSP. Sponsored by the CDC, multiple standardization-certification programs provide accuracy-based standards for tests across manufacturers and methods. The CDC Hormone Standardization (HoSt) Program, for example, aims to provide more-accurate and precise steroid hormone tests for patient care. The differences among manufacturers' assays for hormone tests may actually be due to high concentrations of steroid-binding proteins present in serum, a situation similar to vitamin D.

- Results from different sources/platforms can produce inconsistent answers.
- Inconsistency across assays can impact patient care.

What is the CDC Vitamin D Standardization Program?

The National Institutes of Health Office of Dietary Supplements (NIH ODS) launched the Vitamin D Standardization Program (VDSP) in 2010 to correct disparities in different manufacturers' 25-hydroxyvitamin D results. The VDSP is a collaboration of the NIH ODS, National Institutes of Health, Centers for Disease Control and Prevention, National Institute for Standards and Technology, and Ghent University in Belgium.

- An initiative of the National Institutes of Health Office of Dietary Supplements.
- Created to correct disparities among various vitamin D assays; disparities that were sometimes large enough to impact patient care.

How does the Vitamin D Standardization Program work?

The VDSP develops protocols for standardizing 25-hydroxyvitamin D measurement in national health/nutrition surveys to improve public health. In addition, the CDC introduced the two-phase Vitamin D Standardization-Certification Program (VDSCP). In the first phase, participants receive 40 single-donor serum samples with value assignments from a JCTLM-recognized reference method. Participants must use these samples to verify their immunoassay calibrations and establish metrological traceability according to ISO 17511.1.

Once calibrations are verified in phase one, the CDC requires participants to complete quarter challenges with 10 blinded samples. This is phase two, and it monitors the stability of the participants' calibrations over time. After the participant passes four consecutive surveys, it is certified for one year.¹ Renewal occurs annually. The performance criteria for vitamin D are a 5% mean bias and 10% imprecision.

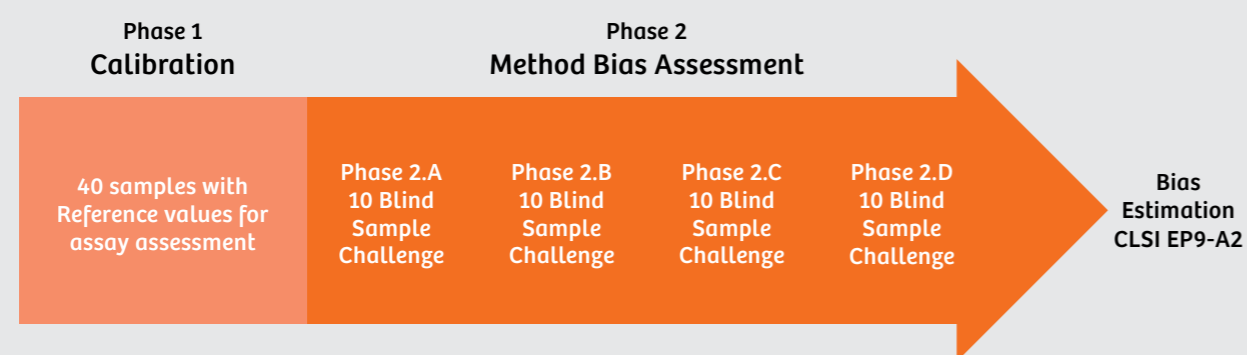
- There are two phases:
 - In phase one, immunoassay calibrations are verified.
 - In phase two, stability of calibrations is monitored.
- Once certified, renewal occurs annually.

Which vendors are currently CDC-VDSCP certified?

Laboratories that successfully passed the performance criteria of $\pm 5\%$ mean bias to the CDC and University of Ghent Vitamin D2 and D3 Reference Method and an overall imprecision of $<10\%$ over the concentration range of 22–275 nmol/L for total 25-hydroxyvitamin D are awarded certificates for successfully completing bias and imprecision testing using specific methods, reagent lots, calibrator lots, and instrumentation.

- Those that pass performance criterion of $\pm 5\%$ mean bias.
- Those with an overall imprecision of $<10\%$ over the concentration range of 22–275 nmol/L for total 25-hydroxyvitamin D.

Phases of the CDC HoSt Program¹



Courtesy of CDC

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Assays are CDC-
VDSCP certified!

https://www.cdc.gov/labstandards/vdscp_participants.html