



# CDC Vitamin D Certification

Frequently Asked Questions

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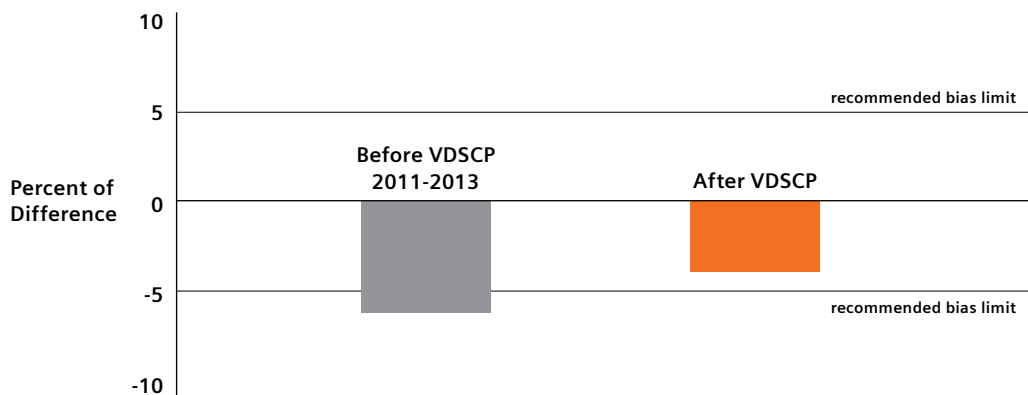
## Why are there differences between Vitamin D results across vendors?

- There are no internationally recognized vitamin D reference materials<sup>1</sup>
- Different methods/materials are used to release vitamin D and standardize the assay<sup>1</sup>
- There is interference from heterophilic antibodies<sup>1</sup>
- There are different calibration materials for patient results<sup>1</sup>

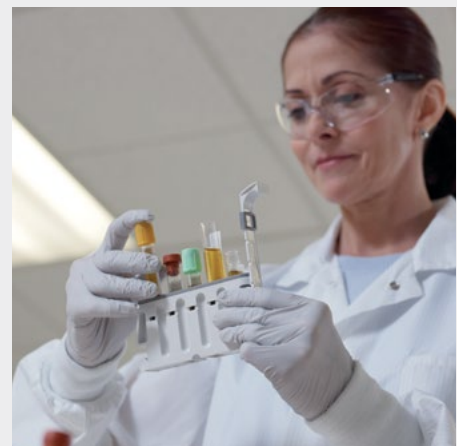
## How did Vitamin D standardization originate?

- It was an initiative of the National Institutes of Health Office of Dietary Supplements – the Vitamin D Standardization Program (VDSP) – to correct disparities among various vitamin D assays, some that impacted patient care<sup>1</sup>
- Today, the CDC's Vitamin D Standardization-Certification Program (VDSCP) and CDC Laboratory/Manufacturer Hormone Standardization (HoSt) Program exist to provide reference measurements, evaluate the accuracy and reliability of vitamin D tests and certify those that have a certain accuracy and precision<sup>2,7</sup>
- The CDC Reference Method Laboratory (RMP) uses a unique, highly accurate and precise reference method that meets stringent analytical performance criteria<sup>3</sup>

Improvement in Mean Bias\* among VDSCP Participants<sup>2</sup>



\*The difference between the average of measurements of vitamin D made by VDSCP participants and the CDC-assigned reference value



## Why is Vitamin D standardization and certification important?

- Inconsistency across assays can impact patient care<sup>1</sup>
- Standardization-Certification ensures methods are accurate and reliable<sup>2</sup>
- Quarterly performance assessments and yearly re-certification ensure tests remain accurate and reliable<sup>4,5</sup>

## Which vendors are currently CDC certified?

- Laboratories that successfully pass the performance criteria are awarded certificates for one year<sup>5</sup>
- Siemens Vitamin D Total assays for Atellica IM, ADVIA Centaur CP/XP/XPT, and Dimension EXL LOCI are VDSCP Certified<sup>6</sup>

### Analytical performance criteria for routine tests used to measure total 25-hydroxyvitamin D<sup>4</sup>

Maximum Allowable Mean Bias*	Maximum Allowable Imprecision (Coefficient of Variation)
+/-5.0%	<10.0%

\*Bias to the reference method.

## How does the Vitamin D Standardization-Certification Program (VDSCP) work?

- Participants obtain detailed information about the analytical biases and precision of their vitamin D tests in a 2 phased process<sup>4</sup>
  1. There is an initial assessment of the testing performance<sup>4</sup>
  2. It is then followed by enrollment in the actual certification process<sup>4</sup>

Phase 1 Assessment/Improvement (samples with known targets)	Phase 2 Evaluation/Certification (blinded samples)
Laboratory tests and evaluates its performance using 40 samples	Quarterly performance monitoring with 10 blinded samples per quarter
Laboratory identifies and eliminates measurement problems	Evaluation and certification of performance using data from 4 consecutive quarters
Optional (enrollment not necessary for certification)	

The CDC has certified the ADVIA Centaur<sup>®</sup> Vitamin D Total assay, the Atellica<sup>®</sup> IM Vitamin D Total assay, and the Dimension<sup>®</sup> EXL<sup>™</sup> LOCI Vitamin D Total assay. A complete list of certified methods are posted and continually updated on the CDC website.

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An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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<sup>1</sup><https://www.aacc.org/publications/cln/articles%2013/august/vitamin-dstandardization>

<sup>2</sup><https://www.cdc.gov/labstandards/vdscp.html>

<sup>3</sup>[https://www.cdc.gov/labstandards/vdscp\\_laboratory.html](https://www.cdc.gov/labstandards/vdscp_laboratory.html)

<sup>4</sup>[https://www.cdc.gov/labstandards/vdscp\\_procedures.html](https://www.cdc.gov/labstandards/vdscp_procedures.html)

<sup>5</sup>[https://www.cdc.gov/labstandards/vdscp\\_participants.html](https://www.cdc.gov/labstandards/vdscp_participants.html)

<sup>6</sup>[https://www.cdc.gov/labstandards/pdf/hs/CDC\\_Certified\\_Vitamin\\_D\\_Procedures-508.pdf](https://www.cdc.gov/labstandards/pdf/hs/CDC_Certified_Vitamin_D_Procedures-508.pdf)

<sup>7</sup>[https://www.cdc.gov/labstandards/hs\\_standardization.html](https://www.cdc.gov/labstandards/hs_standardization.html)

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