Consistent and Clinically Accurate Vitamin D Results with Standardization

Siemens Standardizes Vitamin D Total Assay to ID-LC/MS/MS Reference Measurement Procedure

Measurement and monitoring of 25(OH)vitamin D is important in patients who are suspected of vitamin D insufficiency or deficiency contributing to underlying diseases affecting bone and calcium metabolism. While physicians have had access to a variety of assays and methods for vitamin D measurement, there has been an historical lack of standardization, leading to inconsistent results among assays. This has reduced confidence that longitudinal changes in patient values are truly due to clinical fluctuations.[1-6]

For this reason, the NIH Office of Dietary Supplements (ODS) instituted the Vitamin D Standardization Program (VDSP) in November 2010. As a collaborative effort of the National Institute of Standards and Technology (NIST), the Centers for Disease Control and Prevention (CDC), and Ghent University (Ghent, Belgium), the program goal is to provide laboratories and manufacturers with reference materials and a reference protocol to standardize the laboratory measurement of vitamin D.[2,7-10] To complement this program, manufacturers and laboratories may participate in a certification process administered by the CDC: the Vitamin D Standardization—Certification Program (VDSCP).[11]

Method comparison studies

Siemens Healthcare Diagnostics has standardized its Vitamin D Total assay to the Ghent University ID-LC/MS/MS 25(OH)vitamin D reference measurement procedure (RMP), one of the two reference procedures for the VDSP. Two independent method comparison studies (Table 1, Figures 1 and 2) confirm that the ADVIA Centaur® Vitamin D Total assay demonstrates values equivalent to the Ghent RMP, thus verifying the assay's standardization. This indicates that the calibration of the assay can be relied upon to report accurate vitamin D levels, because the Ghent method is known to accurately measure 25(OH) vitamin D_2 and 25(OH)vitamin D_3.

Table 1. Pearson correlation coefficient and Deming regression results by method compared to Ghent University's ID-LC/MS/MS 25(OH)vitamin D RMP.

Study	1	2
Pearson correlation coefficient (r)	0.96	0.99
Slope	0.99	0.96
Intercept (ng/mL)	0.53	2.89
N	177	122

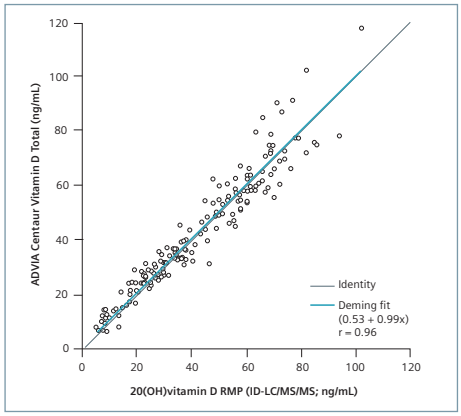

Figure 1. Study 1: Deming regression analysis comparing the ADVIA Centaur Vitamin D Total assay and the RMP.

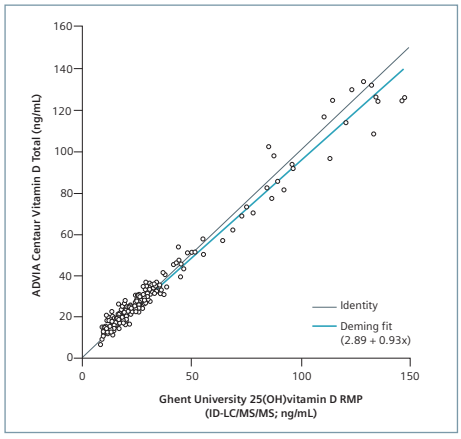

Figure 2. Study 2: Deming regression analysis comparing the ADVIA Centaur Vitamin D Total assay and the RMP.

CDC VDSCP Program

As a complement to the VDSP, the CDC has instituted a certification program for laboratories and manufacturers. To become VDSCP-certified, participants must pass four consecutive quarterly challenges using blinded samples after an initial calibration period. Samples are value-assigned using the Ghent RMP and supplied to participants by the CDC. Results are analyzed by the CDC according to CLSI document EP9-A2 and used to determine bias, precision, and total error.[11,12] In order to receive certification, the mean bias for all 40 samples (160 results) determined using the subject assay must be within 5% of the CDC values, and overall imprecision must be ≤10%. The program is ongoing, and certification must be renewed annually. Current information can be found at www.cdc.gov/labstandards/hs_standardization.html.

The Siemens ADVIA Centaur Vitamin D Total assay was one of the first assays to achieve certification through this program. The ADVIA Centaur Vitamin D Total assay performed well within the acceptance criteria (Figure 3).

Correlation between the CDC RMP-assigned sample values and the ADVIA Centaur Vitamin D Total assay values were highly correlated (r=0.96) combining all four quarterly blind trials. The mean bias was 0.3% (SD = 16.8; 95% CI = –5.0 to 5.6) and the mean CV was 5.5% (SD = 3.2; 10th percentile = 1.6%, 90th percentile = 9.8%).

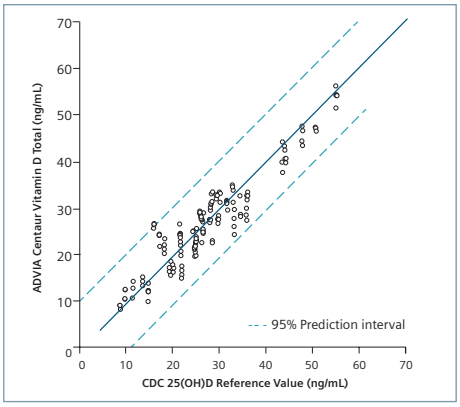

Figure 3. Linear regression generated by the CDC VDSCP from all challenge samples in 2013.

The CDC certification attests to the accuracy of the Siemens ADVIA Centaur Vitamin D Total assay and its standardization to the Ghent RMP specified by the VDSP. This certification indicates that the Siemens ADVIA Centaur Vitamin D Total assay is fit for use in the clinical laboratory and can be relied upon to report patient vitamin D status accurately.

To learn more about the standardized ADVIA Centaur Vitamin D Total assay, please visit **www.siemens.com/vitamindtotal**

References:

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