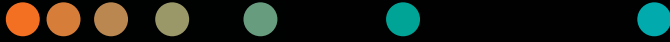


Vitamin D Total Assay

The only CDC certified method with defined pediatric expected values



Ranges established for pediatrics

- Easily adopt Atellica® IM and ADVIA Centaur® Vitamin D Total assay pediatric reference ranges*
- Optimize clinical operations by reducing lab costs and resources associated with establishing ranges.*
- Reduce the potential for over-recovery and risk of missed deficiency, with only 1% cross-reactivity to 3-epi-25(OH)vitamin D3
- Prevent underestimation of results with equimolar detection of vitamin D2 (104.5%) and D3 (100.7%)

Based on the 95% confidence interval, the following pediatric values were obtained:^{5,6}

	Specimen type	Observed values, pediatric (12 months up to 21 years)
Median 25(OH) vitamin D	Serum	23.8 ng/mL (59.5 nmol/L)
Observed range 2.5th to 97.5th percentile	Serum	11.4–45.8 ng/mL (28.5–114.5 nmol/L)

**Pediatric reference ranges are available for Atellica IM and ADVIA Centaur. As with all in vitro diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only. Refer to CLSI EP28-A3c for recommendations on establishing and verifying ranges.*

Atellica IM and ADVIA Centaur Vitamin D Total reference values were established in accordance with CLSI guideline EP28-A3c using adult and pediatric serum samples.

The pediatric serum samples used to establish the pediatric reference values included:^{5,6}

- 237 apparently healthy male and female subjects of light and dark skin types:
 - 32 between the ages of 1-3 years
 - 114 from 3-12 years
 - 91 from 13-21 years
- Samples from different seasons
- Samples from different geographical regions of the United States
- Samples with normal values for PTH and TSH

Expected pediatric values based on literature reviewed by Siemens Healthineers:

Vitamin D Status	Range, Pediatric
Deficiency	< 15 ng/mL (37.5 nmol/L)
Insufficiency	15– < 20 ng/mL (37.5– < 50 nmol/L)
Sufficiency	20–100 ng/mL (50–250 nmol/L)

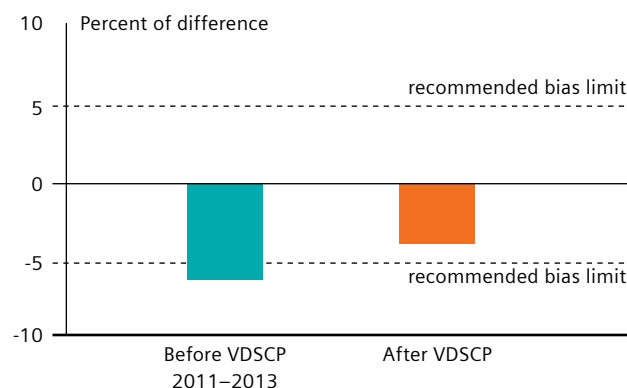
[siemens-healthineers.us/Vitamin-D](https://www.siemens-healthineers.us/Vitamin-D)

CDC Certification (VDSCP*)^{1,2,3}

- Ensures accuracy and reliability of vitamin D testing using well established procedures
- Certifies those methods that have a certain accuracy and precision:
 - Maximum allowable bias of $\leq 5\%$
 - Maximum allowable imprecision of $< 10\%$
- Program participation requires quarterly performance assessments for re-certification

*Vitamin D Standardization-Certification Program

According to the CDC, there is an improvement in *Mean Bias among VDSCP participants:¹



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

The CDC has certified the following assays from Siemens Healthineers:^{3,4}

- The ADVIA Centaur® Vitamin D Total assay
- The Atellica® IM Vitamin D Total assay
- The Dimension® EXL™ LOCI Vitamin D Total assay

A complete list of certified methods/vendors are posted and continually updated on the CDC website.

¹<https://www.cdc.gov/labstandards/vdscp.html>

²https://www.cdc.gov/labstandards/vdscp_procedures.html

³https://www.cdc.gov/labstandards/vdscp_participants.html

⁴https://www.cdc.gov/labstandards/pdf/hs/CDC_Certified_Vitamin_D_Procedures.pdf

⁵Atellica IM Analyzer Vitamin D Total (VitD)

⁶ADVIA Centaur, ADVIA Centaur XP, ADVIA XPT Immunoassay Systems Vitamin D Total (VitD)

Siemens Healthineers Headquarters

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

USA

Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005, USA
Phone: +1-914-631-8000
siemens-healthineers.us

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