

[www.siemens.com/vitamindtotal](http://www.siemens.com/vitamindtotal)

# ADVIA Centaur Vitamin D Total Assay\* Specifications

Vitamin D Total Assay on the ADVIA Centaur XP System

The Siemens Healthcare Diagnostics ADVIA Centaur® Vitamin D Total assay\* is a one-pass immunoassay, designed with a competitive format architecture that uses a proprietary anti-fluorescein labeled (FITC) monoclonal antibody covalently bound to paramagnetic particles (PMP), one monoclonal antibody labeled with acridinium ester (AE), and a vitamin D analog labeled with fluorescein.

## Advantages

- Traceable to the 25(OH)vitamin D Reference Method Procedure (RMP)<sup>1,2</sup>
- Clinical accuracy with a total 25(OH)vitamin D value
- Reproducible results
- Increased productivity and consolidated testing

## Outstanding Assay Performance

- Equimolar measurement of total 25(OH)vitamin D<sub>2</sub> and D<sub>3</sub>
- Fast turnaround time—ADVIA Centaur XP: 18 minutes
- Minimal (1.1%) cross-reactivity to 3-Epi 25(OH)vitamin D<sub>3</sub>
- Broad dynamic assay range: 4.2–150 ng/mL
- Good precision: 4.2%–11.9% CV

## Intended Use

The ADVIA Centaur Vitamin D Total assay is for in vitro diagnostic use in the quantitative determination of total 25(OH)vitamin D in human serum and plasma (EDTA, lithium-heparin, sodium-heparin) on the ADVIA Centaur and ADVIA Centaur XP systems. It is intended as an aid in the determination of vitamin D sufficiency.

## Clinical Utility<sup>3</sup>

Vitamin D is a fat-soluble hormone involved in the intestinal absorption of calcium and regulation of calcium. It plays a vital role in the formation and maintenance of strong, healthy bones. Vitamin D deficiency has long been associated with rickets in children and osteomalacia in adults; and long-term insufficiency of calcium and vitamin D leads to osteoporosis. Additionally, in recent years, vitamin D levels have become an indicator of general health status, and there have been multiple publications linking vitamin D deficiency to several disease states, such as cancer, cardiovascular disease, diabetes, and autoimmune diseases.

## ADVIA Centaur System—Maximizing Satisfaction

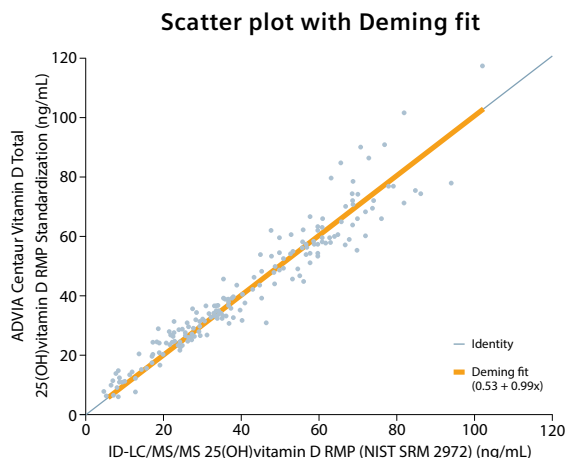
### Optimal productivity:

- ADVIA Centaur XP System—up to 240 tests per hour
- Comprehensive menu including anemia, bone metabolism, cardiovascular, fertility, infectious disease, oncology, TDM, and thyroid

\* Not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements.

## Standardization

The assay is standardized using internal standards which are traceable by method correlation to Ghent University's ID-LC/MS/MS 25(OH)vitamin D RMP. The ID-LC/MS/MS RMP is traceable to the NIST SRM 2972<sup>2,3</sup>. A correlation comparing ID-LC/MS/MS 25(OH) vitamin D RMP to the ADVIA Centaur Vitamin D Total assay was performed with 177 serum samples, yielding a Deming slope of 0.99, intercept of 0.53, and regression coefficient of 0.96.



1. Sempos CT, Vesper HW, Phinney KW, Thienpont LM, Coates PM, Vitamin D Standardization Program (VDSP). Vitamin D status as an international issue: National surveys and the problem of standardization. *Scandinavian Journal of Clinical & Laboratory Investigation*, 2012; 72(Suppl 243): 32 -40
2. Thienpont L, Stepman HCM, Vesper HW. Standardization of measurements of 25-Hydroxyvitamin D3 and D2. *Scandinavian Journal of Clinical & Laboratory Investigation*, 2012; 72(Suppl 243): 41 -49
3. Dietary Supplemental Fact Sheet: Vitamin D. Office of Dietary Supplements. National Institutes of Health. Updated 11/13/2009. Accessed 08/17/2010.

## Vitamin D Total Performance Summary

	Sample Type	Sample Volume	Assay Range	Limit of Quantitation	Onboard Stability	Calibration Interval	Calibrator Stability
<b>ADVIA Centaur XP</b>	Serum/Plasma	20 µL	4.2–150 ng/mL	4.2 ng/mL	28 days	28 days	28 days

Ordering Information		
10699201	1 ReadyPack® primary reagent pack of ADVIA Centaur VitD with calibrator	100 tests
10699533	5 ReadyPack primary reagent packs of ADVIA Centaur VitD with calibrator	500 tests
10699200	ADVIA Centaur VitD quality control material (3-pk)	2 x 3

Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

ADVIA Centaur, ReadyPack, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc. All other trademarks and brands are the property of their respective owners.

Not available for sale in the U.S.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

### Global Siemens Headquarters

Siemens AG  
Wittelsbacherplatz 2  
80333 Muenchen  
Germany

### Global Siemens Healthcare Headquarters

Siemens AG  
Healthcare Sector  
Henkestrasse 127  
91052 Erlangen  
Telephone: +49 9131 84 -0  
Germany  
[www.siemens.com/healthcare](http://www.siemens.com/healthcare)

### Global Division

Siemens Healthcare Diagnostics Inc.  
511 Benedict Avenue  
Tarrytown, NY 10591-5005  
USA  
[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

Order No. A91DX-CAI-130359-XC1-4A00  
07-2013 | All rights reserved  
© 2013 Siemens Healthcare Diagnostics Inc.