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 Measurement Procedure (RMP)\(^1,2\)
- Clinical accuracy with a total 25(OH)vitamin D value
- Reproducible results
- Increased productivity and consolidated testing
- Certified procedure of the CDC Vitamin D Standardization-Certification Program (VDSCP)\(^3\)

**Outstanding Assay Performance**

- Equimolar measurement of total 25(OH)vitamin D\(_2\) and D\(_3\)
- Fast turnaround time — ADVIA Centaur XP: 18 minutes
- Minimal (1.1%) cross-reactivity to 3-epi-25(OH)vitamin D\(_3\)
- 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 XP systems. It is intended as an aid in the determination of vitamin D sufficiency.

**Clinical Utility**\(^4\)

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
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 2972.1. A correlation comparing ID-LC/MS/MS 25(OH) vitamin D RMP to the ADVIA Centaur Vitamin D Total assay was performed with 122 serum samples, yielding a Deming slope of 0.93, intercept of 2.89, and regression coefficient of 0.99.

Vitamin D Total Performance Summary

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Sample Volume</th>
<th>Assay Range</th>
<th>Limit of Quantitation</th>
<th>Onboard Stability</th>
<th>Calibration Interval</th>
<th>Calibrator Stability</th>
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</thead>
<tbody>
<tr>
<td>ADVIA Centaur XP</td>
<td>Serum/Plasma</td>
<td>20 µL</td>
<td>4.2–150 ng/mL</td>
<td>4.2 ng/mL</td>
<td>28 days</td>
<td>28 days</td>
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Ordering Information

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<tr>
<th>Order No.</th>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>10699201</td>
<td>1 ReadyPack® primary reagent pack of ADVIA Centaur VitD with calibrator</td>
<td>100 tests</td>
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<tr>
<td>10699533</td>
<td>5 ReadyPack primary reagent packs of ADVIA Centaur VitD with calibrator</td>
<td>500 tests</td>
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<tr>
<td>10699200</td>
<td>ADVIA Centaur VitD quality control material (3-pk)</td>
<td>2 x 3</td>
</tr>
</tbody>
</table>


† www.cdc.gov/labstandards/hs_procedures.html