The Siemens Healthcare Diagnostics ADVIA Centaur® Vitamin D Total assay is a one-pass competitive immunoassay 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

• Provide accuracy with a total 25(OH) vitamin D value
• Ensure reproducible results
• Increase productivity and consolidate testing

Outstanding Assay Performance

• Equimolar measurement of total 25(OH) vitamin D₂ and D₃
• Fast turnaround time — ADVIA Centaur XP: 18 minutes
• Traceable to LC/MS/MS
• Broad dynamic assay range: 4.2–150 ng/mL
• Excellent precision: 4.8%–11.1% 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

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 has become an assay 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
Method Comparison Data

A study was carried out on 113 randomly selected leftover samples obtained from a clinical laboratory. The samples were split and run on the ADVIA Centaur Vitamin D Total assay, the DiaSorin LIAISON 25 OH Vitamin D TOTAL assay and LC/MS/MS. The DiaSorin LIAISON 25 OH Vitamin D TOTAL assay was run at an independent laboratory following the assay’s IFU. The LC/MS/MS was run at a reference laboratory following internal method procedures for LC/MS/MS. The data analyzed by Deming regression is presented below.

### ADVIA Centaur Vitamin D Total Assay vs. LC/MS/MS

\[
\text{ADVIA Centaur Vitamin D Total} = 1.08 \times (\text{LC/MS/MS}) + 4.11 \text{ ng/mL}, \quad r = 0.77
\]

### ADVIA Centaur Vitamin D Total Assay vs. DiaSorin LIAISON 25 OH Vitamin D TOTAL Assay

\[
\text{ADVIA Centaur Vitamin D Total} = 1.15 \times (\text{DiaSorin LIAISON 25 OH Vitamin D TOTAL}) + 0.70 \text{ ng/mL}, \quad r = 0.91
\]

### ADVIA Centaur Vitamin D Total Assay and DiaSorin LIAISON 25 OH Vitamin D TOTAL Assay vs. LC/MS/MS

\[
\text{ADVIA Centaur Vitamin D Total Assay} = 0.95 \times (\text{LC/MS/MS}) + 2.90 \text{ ng/mL}, \quad r = 0.92
\]

\[
\text{DiaSorin LIAISON 25 OH Vitamin D TOTAL} = 0.87 \times (\text{LC/MS/MS}) - 0.80 \text{ ng/mL}, \quad r = 0.77
\]

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>Code</th>
<th>Description</th>
<th>Quantity</th>
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</thead>
<tbody>
<tr>
<td>10491994</td>
<td>1 ReadyPack® primary reagent pack of ADVIA Centaur VitD</td>
<td>100 tests</td>
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<tr>
<td>10631021</td>
<td>5 ReadyPack primary reagent packs of ADVIA Centaur VitD</td>
<td>500 tests</td>
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<tr>
<td>10632229</td>
<td>ADVIA Centaur VitD QC (3-pk)</td>
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<tr>
<td>10630911</td>
<td>ADVIA Centaur VitD Calibrator (6-pk)</td>
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