**Clinical Application**

A very common clinical application of Vitamin D testing is for the diagnosis and treatment of Vitamin D deficiency which leads to impaired bone metabolism including:

- Rickets
- Osteomalacia
- Osteoporosis

Vitamin D has a regulatory role for genes and receptors in cells and Vitamin D levels are associated with:

- Immune system activity
- Prevention of certain cancers (e.g. colorectal cancer)
- Cardiovascular disease prevention
- Osteoarthritis
- Fetus development
- Risk for preeclampsia
- Insulin resistance
- Mortality

Vitamin D deficiency is frequently undiagnosed and the most important molecule to measure Vitamin D status of the body is 25-OH Vitamin D.

**Physiology**

Vitamin D is a fat-soluble steroid prohormone. Of the two major forms Ergocalciferol (D2) and Cholecalciferol (D3) only Vitamin D3 is synthesized by the body. Main Vitamin D sources for humans are UV exposure from sun, which leads to cholecalciferol production in the upper layers of the skin, food like fish, sea shells, mushrooms, Vitamin D2 fortified food (e.g. milk) and supplements. Only an estimated 10–20% of Vitamin D is supplied through nutritional intake. Vitamin D is converted to the active hormone 1,25-(OH)2-Vitamin D (Calcitriol) through two hydroxylation reactions. The major storage form of Vitamin D is 25-OH Vitamin D.

Vitamin D plays a major role in the calcium and phosphorus homeostasis. Vitamin D deficiency is a cause of hyperparathyroidism and diseases related to impaired bone metabolism (like rickets, osteoporosis, osteomalacia). It is known that most cells express the Vitamin D receptor and about 3% of the human genome is directly or indirectly regulated by the Vitamin D endocrine system.

**ARCHITECT**

25-OH VITAMIN D

Put science on your side.
ASSAY CHARACTERISTICS

Systems
ARCHITECT i2000sr, i1000sr, ci4100, ci8200, ci16200

Method and format
1 Step Delayed Chemiluminescent Microparticle Immunoassay (CMIA) with Automated Online Pre-treatment

Time to first result
36 minutes

Throughput
Up to 100 tests per hour

Assay range
0.0–160.0 ng/mL (400.0 nmol/L)

Calibrators
6 points 0.0–160.0 ng/mL

Test kit sizes
1 x 100 and 1 x 500 Test Formats

Interfering substances
≤10% for all common interferences

Reagent stability
On board: 500 test kit 14 days, 100 test kit 7 days

Calibration stability
7 days

Sensitivity
LoB 1.9 ng/mL, LoD 3.1 ng/mL and LoQ 8.0 ng/mL

Sample volume
Priority loading: 60 μL for first run, 10 μL for each additional run
≤3 hours on board: 150 μL for first run 10 μL for each additional run

Sample type
Human serum (including serum collected in serum separator tubes)
Human plasma collected in:
• Potassium-EDTA
• Sodium Citrate
• Sodium Heparin
• Lithium Heparin (powder or gel)

Sample stability
Specimens may be stored on or off the clot, red blood cells, or separator gel for:
• up to 12 days at 2–8 °C or
• up to 72 hours at 15–30 °C

PRECISION

<table>
<thead>
<tr>
<th>Sample</th>
<th>Reagent Lot</th>
<th>N</th>
<th>Mean Conc. (ng/mL)</th>
<th>Within Run</th>
<th>Total</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SD %CV</td>
<td>SD %CV</td>
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<tr>
<td>Low Control</td>
<td>1 80</td>
<td>19.0</td>
<td>0.709  3.7</td>
<td>0.712  3.8</td>
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<td></td>
<td>2 80</td>
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<td>0.889  4.6</td>
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<tr>
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<td>1.142  3.0</td>
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<tr>
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<td>1.062  2.8</td>
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<tr>
<td>High</td>
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<td>78.4</td>
<td>1.470  3.1</td>
<td>0.912  4.0</td>
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<tr>
<td>Control</td>
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<td>1.485  1.9</td>
<td>2.034  2.7</td>
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<tr>
<td>Serum Panel 1</td>
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<td>0.714  3.1</td>
<td>0.912  4.0</td>
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<tr>
<td></td>
<td>2 80</td>
<td>22.4</td>
<td>0.548  2.4</td>
<td>0.780  3.5</td>
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<td>Serum Panel 2</td>
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<td>2 80</td>
<td>71.3</td>
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ORDERING INFORMATION

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<thead>
<tr>
<th>Description</th>
<th>List Number</th>
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<tbody>
<tr>
<td>ARCHITECT 25-OH Vitamin D Reagent: 100 tests</td>
<td>3L52-25</td>
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<tr>
<td>ARCHITECT 25-OH Vitamin D Reagent: 500 tests</td>
<td>3L52-35</td>
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<tr>
<td>ARCHITECT 25-OH Vitamin D Calibrators (6 levels: A–F)</td>
<td>3L52-01</td>
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<tr>
<td>ARCHITECT 25-OH Vitamin D Controls (3 levels: Low, Medium, and High)</td>
<td>3L52-10</td>
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<tr>
<td>ARCHITECT Assay CD-ROM</td>
<td>1L66-08 or higher</td>
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</table>

2 All data is characterization performance data from assay insert.

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