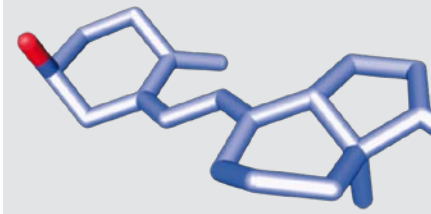




ARCHITECT 25-OH VITAMIN D



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.¹ 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.

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.

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ASSAY CHARACTERISTICS

Systems	ARCHITECT <i>i</i> 2000sR, <i>i</i> 1000sR, <i>ci</i> 4100, <i>ci</i> 8200, <i>ci</i> 16200
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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • up to 12 days at 2–8 °C or • up to 72 hours at 15–30 °C

PRECISION²

Sample	Reagent Lot	N	Mean Conc. (ng/mL)	Within Run		Total	
				SD	%CV	SD	%CV
Low	1	80	19.0	0.709	3.7	0.712	3.8
Control	2	80	19.5	0.589	3.0	0.889	4.6
Medium	1	80	38.5	0.873	2.3	1.142	3.0
Control	2	80	38.0	0.879	2.3	1.062	2.8
High	1	80	78.4	1.470	3.1	0.912	4.0
Control	2	80	76.3	1.485	1.9	2.034	2.7
Serum	1	80	23.0	0.714	3.1	0.912	4.0
Panel 1	2	80	22.4	0.548	2.4	0.780	3.5
Serum	1	80	42.5	1.095	2.6	1.346	3.2
Panel 2	2	80	40.1	0.668	1.7	1.274	3.2
Serum	1	80	75.4	1.088	1.4	2.064	2.7
Panel 3	2	80	71.3	1.242	3.2	1.869	2.6

ORDERING INFORMATION

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

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¹ Pilz S et al. Vitamin D status and arterial hypertension: a systematic review. Nat Rev Cardiol 6, 621–630, 2009.

² All data is characterization performance data from assay insert.

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