

# 25-OH Vitamin D CLIA Microparticles

## Autobio Diagnostics Co., Ltd.

offers more than 600 in vitro diagnostic products including CLIA(microplate based CLIA and magnetic particle based CLIA),ELISA,POCT(Point of Care Test),Microbiology and Biochemistry. As an ISO9001 and EN ISO13485 manufacturer, Autobio supplies high quality products through its well established sales network and is renowned as a reliable partner. For details please visit [en.autobio.com.cn](http://en.autobio.com.cn). Autobio Diagnostics Co., Ltd. | NO.87 Jingbei Yi Rd | National Eco&Tech Zone | Zheng zhou City | China 450016.

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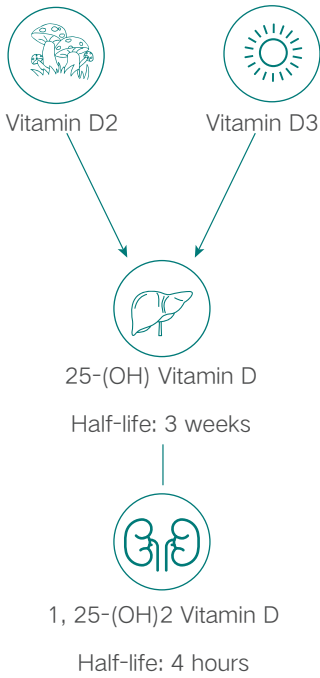


Vitamin D

Vitamin D is a group of fat-soluble secosteroid, which are responsible for increasing intestinal absorption of calcium, magnesium, and phosphate. In humans, vitamin D<sub>2</sub> and vitamin D<sub>3</sub> are the major source of vitamin D and both of them can be ingested from the diet and other supplements. In addition, after sun exposure, the cholesterol in the skin can be synthesized into D<sub>3</sub>. It is also the major natural source of vitamin D [1].

After absorption, Vitamin D is transported to the liver and then converted to 25-(OH) Vitamin D. Subsequently, 25-(OH) Vitamin D converted to 1, 25-(OH)<sub>2</sub> Vitamin D in the kidney which is the bioactive agent regulating the balance of calcium and phosphorus metabolism and bone formation, and is closely related to cardiovascular disease, autoimmune diseases, diabetes, hypertension [2] and etc.

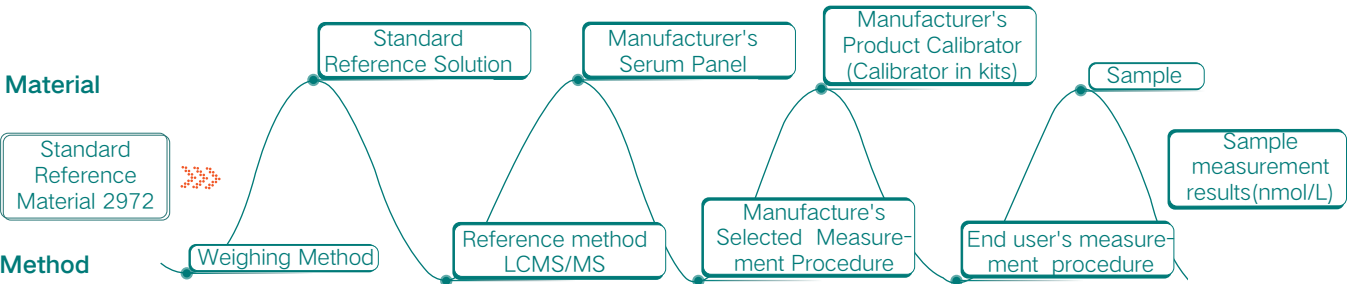
25 -OH Vitamin D is used to estimate the status of Vitamin D.



Assay Characteristics

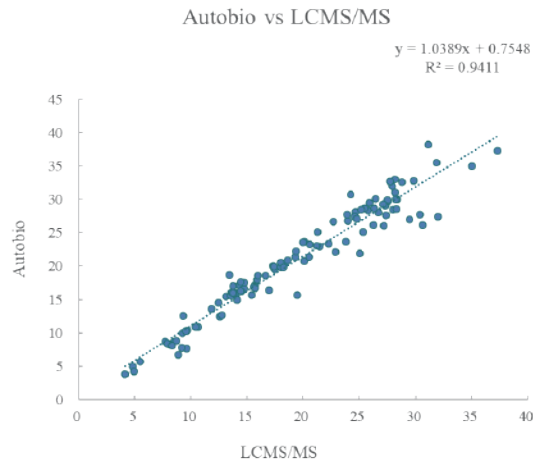
Test Principle	Two-step Sandwich Method
Test Time	34 min
Specimens	Human serum or plasma (EDTA, Heparin or Sodium Citrate)
Sample Volume	10 µL
Measuring Range	2.0 - 150 ng/mL
Limit of Detection	2.0 ng/mL
Onboard stability	28 days

Reliable Traceability Procedure



- National Institute of Standardization and Technology (NIST) Standard Reference Materials (SRM 2972), with assigned reference values, are used to prepare Standard Reference Solution
- LCMS/MS is the gold standard method which was used to determine the Autobio's Serum Panel values
- Autobio Calibrators in the kits could be traceable to SRM 2972 by gold standard method - LCMS/MS

Good Clinical Performance\*



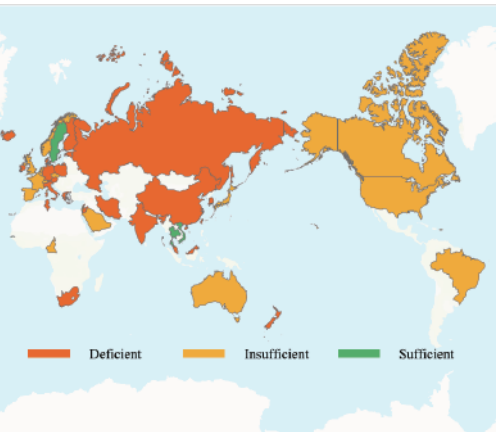
111 clinical samples were tested by Autobio 25-OH Vitamin D and LCMS/MS. Raw data were collected and the correlation analysis was conducted according to corresponding method. Autobio 25-OH Vitamin D showed good correlation with gold standard method - LCMS/MS ( $R^2=0.9411$ )

\*The corresponding data is obtained in a specific laboratory according to the corresponding operation procedures, and the data may vary according to the changes in the environment, operation and other conditions.

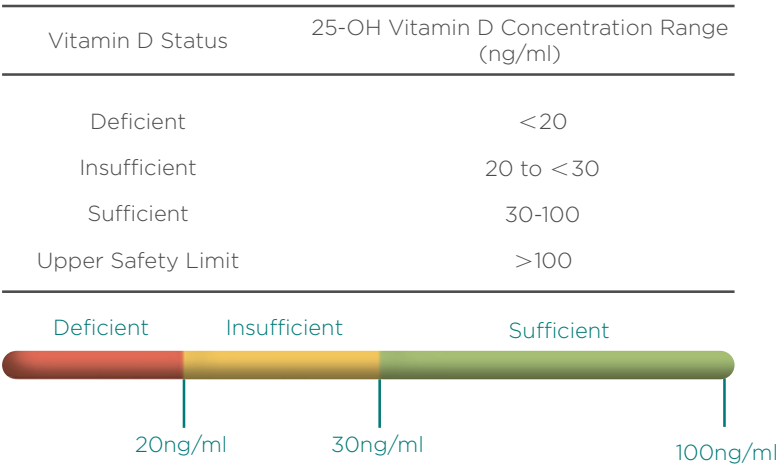
25-OH Vitamin D Deficiency

25-OH Vitamin D deficiency is common globally. A systematic review indicated the vitamin D status in different regions of the world, and 25-OH vitamin D levels < 20 ng/mL were prevalent in a majority of the regions.

Vitamin D deficiency results in abnormalities in calcium, phosphorus, and bone metabolism. Vitamin D regulates the intestinal calcium and phosphorus absorption for bone formation. The vitamin D deficiency can decrease the efficiency of the absorption, subsequently accelerates the osteoclastic activity, creates local foci of bone weakness and causes a generalized decrease in bone mineral density (BMD), resulting in osteopenia and osteoporosis [4].



Country Color Codes of Vitamin D Status in Adults [3]



[1] Calvo M S, Whiting S J, Barton C N. The Journal of nutrition, 2005, 135(2): 310-316.  
[2] Melamed M L, Michos E D, Post W, et al. Archives of internal medicine, 2008, 168(15): 1629-1637.  
[3] Wahl D A, Cooper C, Ebeling P R, et al. Archives of osteoporosis, 2012, 7(1): 155-172.  
[4] Holick M F, Binkley N C, Bischoff-Ferrari H A, et al. The Journal of clinical endocrinology & metabolism, 2011, 96(7): 1911-1930.