

ichroma™ Vitamin D

Quantitative Vitamin D test provides a significant health benefit to users as well as being convenient and affordable. ichroma™ Vitamin D is not only suitable for point-of-care testings, but also in laboratories and hospitals that run smaller volumes of tests.

VDSCP Certified Product

- ichroma™ Vitamin D is certified through Vitamin D Standardization-Certification Program from the CDC each year.
- ichroma™ Vitamin D can quantitatively determine Vitamin D concentration in blood.

Advantages in storage

- Room temperature storage possible.
- Most suitable POCT Vitamin D for hospital and clinic.

User convenience

- Minimum training required.

Fast result time

- Total 28 minutes for the 1st test result.





What is Vitamin D?

Vitamin D, otherwise known as the “Sunshine Vitamin”, plays a major role in helping people achieve good health, including maintaining strong bones and adequate calcium levels in the blood. Unfortunately, more people are working longer hours indoors and thus limiting their sun exposure. Reports now show that over 1 billion people worldwide are vitamin D deficient.¹

While vitamin D deficiency has long been associated with increased risk of rickets and osteoporosis, newer studies show an association with inadequate levels and an increased risk for cardiovascular and autoimmune disease, along with certain types of cancer.¹

Benefits of Vitamin D

- Determine if bone weakness, bone malformation, or abnormal metabolism of calcium (reflected by abnormal calcium, phosphorus, PTH) is occurring as a result of an abnormal level of vitamin D.
- Help diagnose or monitor problems with parathyroid gland function since PTH is essential for vitamin D activation.
- Help monitor the health status of individuals with diseases that interfere with fat absorption, such as cystic fibrosis and Crohn's disease, as vitamin D is a fat-soluble vitamin that is absorbed in the intestine like other lipids.
- Monitor gastric bypass surgery patients as they may not be able to absorb enough vitamin D.
- Help determine the effectiveness of prescribing vitamin D, calcium, phosphorus, and/or magnesium supplements.

When is the test needed?

Since rickets and osteomalacia, the main vitamin D related diseases, is asymptomatic diseases, vitamin D status is needed to test through health check up.

- People with suspected vitamin D deficiency
(e.g. those with persistent, nonspecific musculoskeletal pain, the elderly, housebound people, etc)
- People with suspected toxicity
(e.g. those with anemia of obscure origin, unexplained renal disease, etc)
- People being treated for vitamin D-related disorders

Vitamin D sufficiency levels ^{1, 2}

Vitamin D status	25(OH)D Concentration in blood	
Deficiency	< 10 ng/mL	< 25 nmol/L
Insufficiency	10-30 ng/mL	25-75 nmol/L
Sufficiency	30-100 ng/mL	75-250 nmol/L
Toxicity	> 100 ng/mL	> 250 nmol/L

Conversion factor: ng/mL = 2.5 x nmol/L
Normal serum concentrations

ichroma™ Vitamin D

Test principle

ichroma™ Vitamin D is a fluorescence Immunoassay (FIA) for the quantitative determination of total 25(oh) D2/D3 level in human serum / plasma.



Performance details

• Comparability

25(OH)D concentrations of 79 serum samples were quantified independently with ichroma™ Vitamin D and reference device as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were $y=1.2267X - 2.7861$ and $R = 0.9540$ respectively.

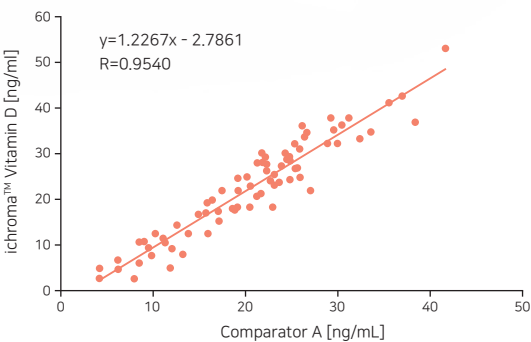


Figure 1. ichroam™ Vitamin D correlation study against comparator A Vitamin D test.

• Specification

Sample type	Serum / Plasma (available EDTA, Heparin, sodium citrate)
Sample volume	50 uL
Assay time	28 min
Measuring range	8.0-70.0 ng/mL (20.0-175.0 nmol/L)
Controls	Available
Storage conditions	Detection tube, Releasing buffer & Detector diluent at 4-30°C (up to 20 months) Cartridges at 4-30°C (up to 20 months)

• References

1. Holick MF. Vitamin D deficiency. N Engl J med 2007;357:266-81.
2. Heaney RP. Functional indexed of vitamin D status and ramifications of vitamin D deficiency. Am J Clin Nutr 2004;80(suppl):1706S-9S.



ichroma™ Vitamin D can apply to

iCHROMA-II

A compact and easy-to-use, fluorescence based POCT immunoassay analyzer.

- High performance with reliability
- Small, compact & light
- Multi test function
- Battery & AC operated
- LIS/HIS compatible



iCHROMA-III

High-throughput immuno-analyzer that enables simultaneous testing for various parameters.

- Random access for various parameters
- Increased throughput
- Patient ID handwriting
- Automatic incubation, reading and disposal of cartridge



Ordering information

Product	Cat. No.	Size	Storage	Shelf Life
ichroma™ Vitamin D	CFPC-47	25 T/Kit	4-30°C for Whole package	20 months
Boditech Vitamin D control	CFPC-102	1 vial	2-8°C	12 months
Inserting tube block	CFPC-80	3 ea/pack	Room temperature	Permanent
ichroma™ II	FPRR021	1 set	Room temperature	
ichroma™ III	FPRR037	1 set	Room temperature	