

○ All tests are quantitative and CE-marked

Product class	Test item	Diseases	Sample type	Reaction time	Measurement ranges
Cardiac	Tn-I	Myocardial infarction	Serum, Plasma	12 min.	0.1-50 ng/mL
	CK-MB	Myocardial infarction	Serum, Plasma	12 min.	3-100 ng/mL
	D-Dimer	Thrombosis	Whole blood, Plasma	12 min.	50-10,000 ng/mL
	Myoglobin	Myocardial infarction	Serum, Plasma	12 min.	5-500 ng/mL
	hsCRP	Cardiovascular inflammation	Whole blood, Serum, Plasma	3 min.	0.1-10 mg/L
Cancer	PSA	Prostate cancer	Whole blood Serum, Plasma	15 min. 15 min.	0.5-100 ng/mL 0.1-100 ng/mL
	AFP	Liver cancer	Serum, Plasma	15 min.	5-350 ng/mL
	CEA	Cancers	Serum, Plasma	12 min.	1-500 ng/mL
	iFOB	Coloerctal cancer	Feces (stool)	10 min.	25-1,000 ng/mL
Diabetes	HbA1c	Diabetes mellitus	Whole blood	12 min.	4-15 %
	Microalbumin	Diabetes mellitus	Urine	12 min.	2-300 mg/L
	Cystatin C	Renal disease	Serum, Plasma	10 min.	0.1-7.5 mg/L
Hormone	TSH	Thyroid malfunction	Serum, Plasma	12 min.	0.1-100 µIU/mL
	TSH WB	Thyroid malfunction	Whole blood	15 min.	1-100 µIU/mL
	TSH Plus	Thyroid malfunction	Whole blood, Serum, Plasma	15 min.	0.4-100 µIU/mL
	T3	Thyroid malfunction	Serum, Plasma	16 min.	0.5-5.0 ng/mL
	T4	Thyroid malfunction	Serum, Plasma	10 min.	20-300 nmol/L
	FSH	Menopause/infertility	Serum, Plasma	15 min.	1-100 mIU/mL
	Progesterone	Fertility	Serum, Plasma	15 min.	1.4-40 ng/mL
	hCG	Pregnancy	Whole blood, Serum, Plasma	15 min.	2-3,000 mIU/mL
	βhCG	Fertility	Serum, Plasma	15 min.	5-50,000 mIU/mL
	LH	Ovulation	Serum, Plasma	15 min.	1-100 mIU/mL
	PRL	Sexual disorder & infertility	Serum, Plasma	10 min.	1-100 ng/mL
	Testosterone	Sexual disorder	Whole blood, Serum, Plasma	12 min.	1-10 ng/mL
	Cortisol	Metabolism	Serum, Plasma	10 min.	80-800 nmol/L
Infection	CRP	Inflammation	Serum, Plasma, Whole blood	3 min.	2.5-300 mg/L
	PCT	Sepsis	Whole blood, Serum, Plasma	12 min.	0.1-100 ng/mL
	ASO	Rheumatic fever	Serum, Plasma	12 min.	25-800 IU/mL
Rheumatoid Arthritis	RF IgM	Rheumatoid Arthritis	Whole blood, Serum, Plasma	5 min.	10-200 IU/mL
Others	Ferritin	Anemia	Serum, Plasma	10 min.	10-1,000 ng/mL
	Vitamin D	Bone disease	Serum, Plasma	28 min.	8 – 70 ng/mL

Shelf life : 20 months at 2-8 °C (Buffer)/ 20 months at 4-30 °C (Cartridge), Markers coming soon: HBsAg, Anti-HBs, HCV

○ Ordering information

Product	Cat. No.	Size	Storage	Shelf Life
ichroma™ Vitamin D	CFPC-47	25T/Kit	2-8 °C for DB and RB / 4-30 °C for Cartridge	20M
ichroma™ Vitamin D Control	CFPO-79	1 vial	2-8 °C	12M
Inserting tube block	CFPO-80	3ea/pack	Room temperature	
i-Chamber	FPRR009	1 set	Room temperature	

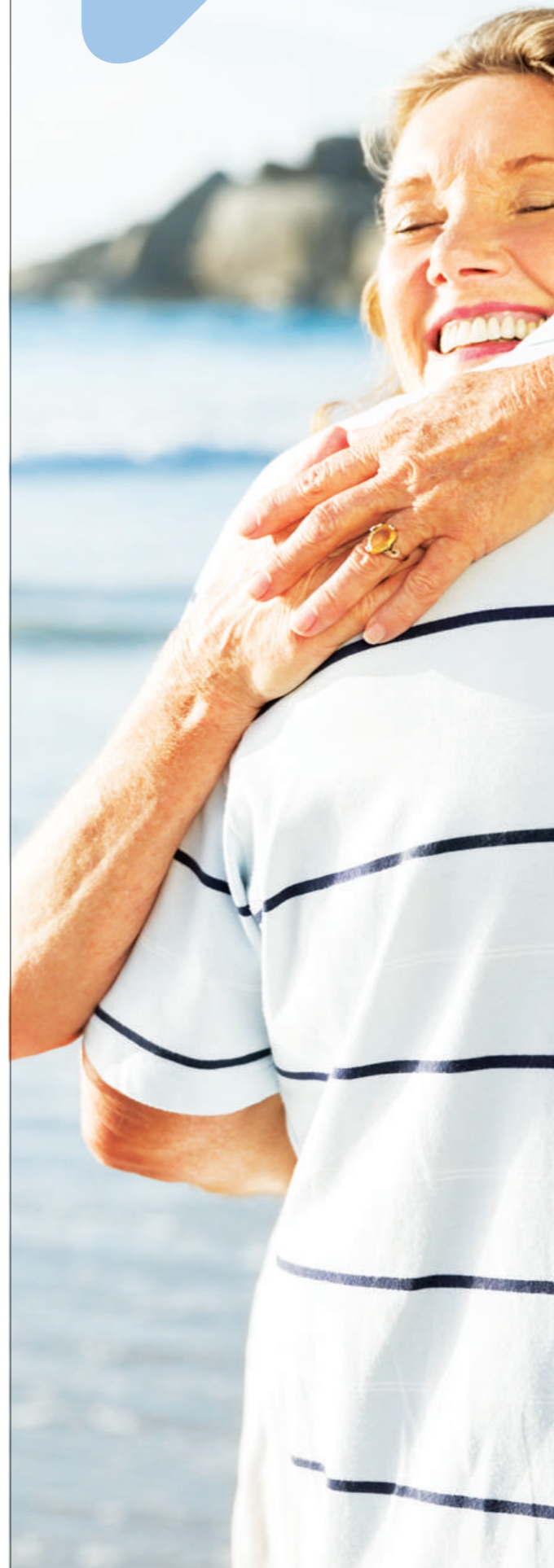
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MADE IN KOREA



# ichroma™ Vitamin D

A quantitative vitamin D test provides significant benefits to users including convenience of use and affordability. ichroma™ Vitamin D is suitable for labs, hospitals and physician offices that run small volumes.

- Short assay time
  - Total 28 minutes for the 1<sup>st</sup> test result
- Easy to use
  - Simple 3-step test procedure:  
1) Test set-up → 2) Sample mixing → 3) Sample loading
  - Minimum training required
- Good reproducibility
  - Less than 15% CV
- Long shelf life
  - 20 months when refrigerated
- Small packing size
  - 25 tests in a kit



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## 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.<sup>1</sup> 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.<sup>1</sup>

## 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 a deficiency or excess of vitamin D.
- Help diagnose or monitor problems with parathyroid gland functioning 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 disease, since vitamin D is a fat-soluble vitamin and is absorbed from the intestine like a fat.
- Monitor people who have had gastric bypass surgery and may not be able to absorb enough vitamin D.
- Help determine the effectiveness of treatment when vitamin D, calcium, phosphorus, and/or magnesium supplementation is prescribed.

## 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<sup>1,2</sup>

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

## ichromax™ Vitamin D

### Test principle

ichromax™ Vitamin D uses a competitive immuno-detection method.

### Performance details

#### Comparability

25(OH)D concentrations of 79 serum samples were quantified independently with ichromax™ Vitamin D and Roche Cobas e411 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.

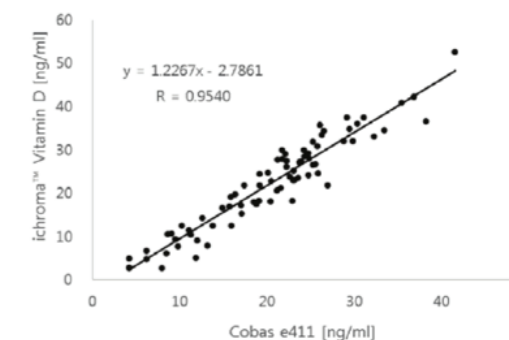


Figure 1. ichromax™ Vitamin D correlation study against Roche Cobas e411 Vitamin D Total assay.

#### Specification

▪ Sample type	Serum / Plasma (available EDTA, Heparin, sodium citrate)
▪ Sample volume	50 uL
▪ Assay time	28 minutes
▪ Measuring range	8.0 - 70.0 ng/mL (20.0-175.0 nmol/L)
▪ Controls	Available
▪ Storage conditions	Detection buffer & releasing buffer at 2-8 °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 indices of vitamin D status and ramifications of vitamin D deficiency. Am J Clin Nutr 2004;80(suppl):1706S-9S.