



## IDS-iSYS 1,25 VitD<sup>Xp</sup>



CKD - MBD



Calcium Metabolism

Fully automated assay for the quantitative determination of 1,25-dihydroxyvitamin D [ $1,25(\text{OH})_2\text{D}$ ] in human serum. The results are used in conjunction with other clinical and laboratory data to assist the clinician in the assessment of vitamin D sufficiency.

The vitamin D compound is biologically inactive but enters the circulation and is hydroxylated in the liver to 25-hydroxyvitamin D [ $25(\text{OH})\text{D}$ ], which is used to determine a patient's vitamin D status. In the kidney,  $25(\text{OH})\text{D}$  is further hydroxylated to produce the physiologically active 1,25-dihydroxyvitamin D [ $1,25(\text{OH})_2\text{D}$ ].  $1,25(\text{OH})_2\text{D}$  is one of the major regulators of calcium and phosphate metabolism, stimulating intestinal calcium absorption and increasing bone resorption. It also inhibits parathyroid hormone (PTH) production both by direct action on the parathyroid glands and indirectly by raising serum calcium levels.  $1,25(\text{OH})_2\text{D}$  production is itself stimulated by parathyroid hormone (PTH), thus providing an effective control loop<sup>1</sup>.

The kidney is the most abundant source of 1-alpha hydroxylase in the body for the conversion of  $25(\text{OH})\text{D}$  to active vitamin D hormone  $1,25(\text{OH})_2\text{D}$ . While 1-alpha hydroxylase also exists in many non-renal tissues for paracrine activation of vitamin D, the circulating level of  $1,25(\text{OH})_2\text{D}$  decreases significantly with diminishing renal function across worsening stages of chronic kidney disease (CKD) contributing to hypocalcemia, secondary hyperparathyroidism (SHPT) and subsequent renal osteodystrophy<sup>2</sup>. Hence, replacement of active vitamin D has been considered an essential step in the management of SHPT and its associated disorders in CKD<sup>3</sup>. Clinical practice guidelines such as the 'Kidney Disease Outcomes Quality Initiatives (KDOQI)' and 'Kidney Disease: Improving Global Outcomes (KDIGO)' suggest the active vitamin D therapeutic regimens in the management of SHPT<sup>4,5</sup>.

### Clinical Value

- Fully automated sample extraction with proven and trusted antibody specificity
- Confidence in patient results through the established automated immunoassay
- Excellent stability combined with on-board storage convenience and reagent handling
- Complete vitamin D and bone markers profile from the same patient sample tube

## Specifications

Format	Fully automated extraction and chemiluminescence immunoassay (CLIA)	
Calibrators	Lyophilised - 3 each of 2 concentration levels, 1.2 mL	
Controls	Lyophilised - 6 each of 2 concentration levels, 1.2 mL	
Limit of Quantification	7.5 pg/mL (18.0 pmol/L)	
Dynamic Range	7.5 - 150 pg/mL (18.0 to 360 pmol/L)	
Reference Range	15.2 to 90.1 pg/mL (36.5 to 216.2 pmol/L)	
Minimum Sample Volume	220 µL plus dead volume	
Sample Type	Human serum including serum collected in serum separator tubes	
Reagent Stability	Immunoextraction cartridge may be stored on-board the system for up to 4 weeks (28 days) Immunoassay cartridge may be stored on-board the system for up to 7 weeks (49 days)	
Calibration Stability	21 days	
Specificity	1,25(OH) <sub>2</sub> D <sub>3</sub>	97%
	1,25(OH) <sub>2</sub> D <sub>2</sub>	72%
	1,24,25(OH) <sub>3</sub> D <sub>3</sub>	106.7%
	25(OH)D <sub>3</sub>	0.04%
	25(OH)D <sub>2</sub>	0.16%
	C3-epimer 25(OH)D <sub>3</sub>	0.00%
	24,25(OH) <sub>2</sub> D <sub>3</sub>	0.06%
	24,25(OH) <sub>2</sub> D <sub>2</sub>	0.00%
	25,26(OH) <sub>2</sub> D <sub>3</sub>	0.52%
	Alfacalcidol	0.01%
	Cholecalciferol	0.00%
	Ergocalciferol	0.00%
	Sensipar	0.00%
	Zemplar (Paracalcitol)	5.70%

## Method Comparison

The IDS-iSYS 1,25 VitD<sup>xp</sup> assay was compared against the IDS-iSYS 1,25-Dihydroxy Vitamin D (IS-2400). A total of 105 samples with values ranging from 11.4 - 150 pg/mL (27.4 - 360 pmol/L) were assayed by each method. Passing-Bablok analysis was performed:

n	Slope	Intercept	Correlation coefficient (r)
105	0.97	6.0 pg/mL	0.94
105	0.97	14.4 pmol/L	0.94

## Ordering Information

Product	Product Code
IDS-iSYS 1,25 VitD <sup>xp</sup> Reagent pack: 100 tests	IS-2000
IDS-iSYS 1,25 VitD <sup>xp</sup> Control Set* Control set: 2 levels	IS-2030

\* Available in selected markets,

Product availability subject to required regulatory approval

Complementary Products	
IDS-iSYS 25-Hydroxy Vitamin D <sup>s</sup>	IS-2700S
IDS-iSYS 1,25-Dihydroxy Vitamin D	IS-2400
IDS-iSYS Intact PTH	IS-3200
IDS-iSYS Ostase <sup>®</sup> BAP	IS-2800
IDS-iSYS Intact PINP	IS-4000
IDS-iSYS TRAcP 5b (BoneTRAP <sup>®</sup> )*	IS-4100

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## References

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- Levin A et al. Prevalence of abnormal serum vitamin D, PTH, calcium, and phosphorus in patients with chronic kidney disease: Results of the study to evaluate early kidney disease. Kidney Int 2007; 71: 31- 38.
- Kovesdy CP et al. Bone and mineral disorders in pre-dialysis CKD. Int Urol Nephrol 2008; 40: 427-440.
- K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. Am J Kidney Dis 2003; 42:Suppl 3:S1-S201.
- Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). Kidney Int. 2009;76 (Suppl 113): S1-S130.