First

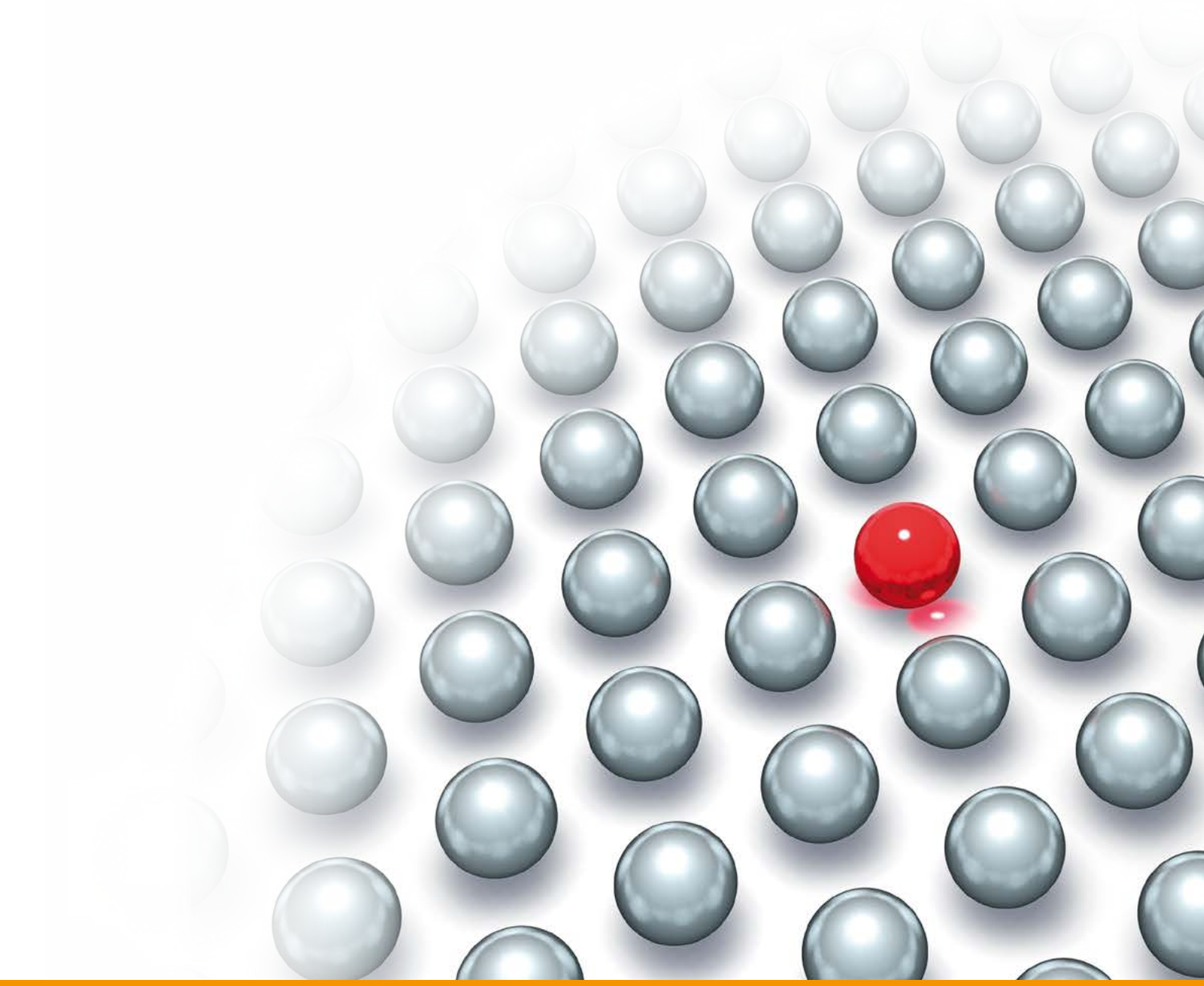
Unique

Automated

LIAISON®

1,25 Dihydroxyvitamin D

First fully automated, extraction free immunoassay for the accurate detection of 1,25 Dihydroxyvitamin D



DiaSorin

The Diagnostic Specialist

FOR OUTSIDE US & CANADA ONLY

Clinical background of 1,25 Dihydroxyvitamin D

1,25 Dihydroxivitamin D is the active form of Vitamin D, its production is tightly regulated through concentration of serum calcium, phosphorus and PTH.

- Low levels can be found in CKD, Vit D dependant rickets type 1, hypophosphatemic rickets, hypoparathyroidism
- High levels in Vit D dependant rickets type 2, sarcoidosis, RA, IBD, primary hyperparathyroidism

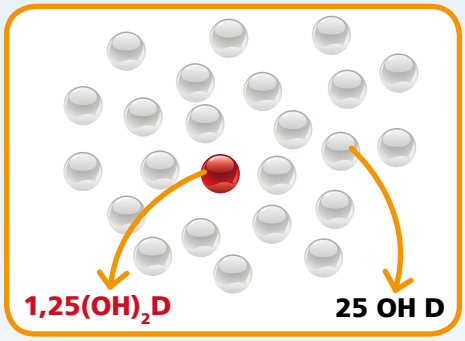
Challenges in 1,25 Dihydroxyvitamin D measurement

Until now, all assays required a long, manual, operator dependant pre-analytical step due to the following facts:

- The molecule circulates in low amounts (pg/mL concentration vs ng/mL concentrations)
- Similarity with its metabolic precursor, 25-OH Vitamin D

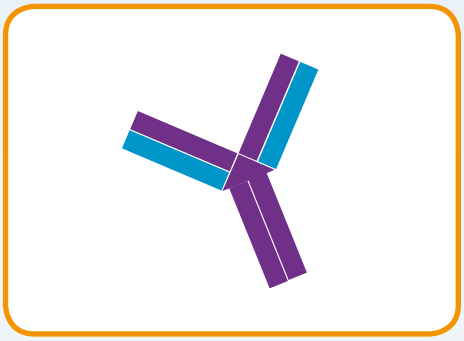
Novel Assay format

The LIAISON® XL 1,25 Dihydroxyvitamin D assay is a modified 3 step sandwich assay that uses a recombinant fusion protein for capture of the $1,25(OH)_2$ D molecule and a murine monoclonal antibody which specifically recognizes the complex formed by the recombinant fusion protein with the $1,25(OH)_2$ D molecule.

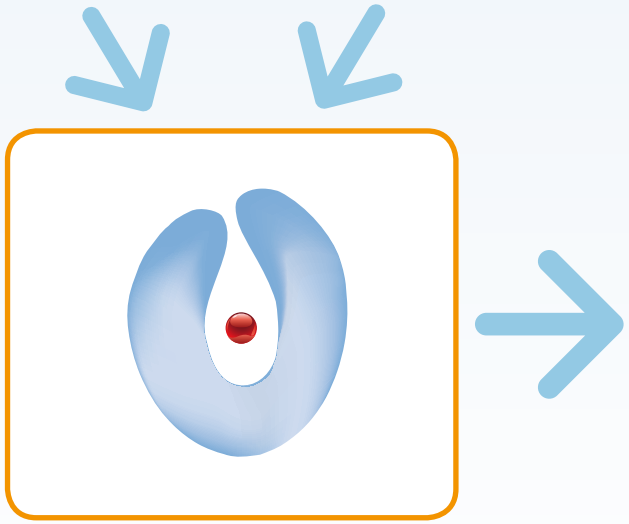


Concentrations of ***1,25(OH)$_2$D*** are normally about 1000-fold lower than the precursor compound 25(OH)D

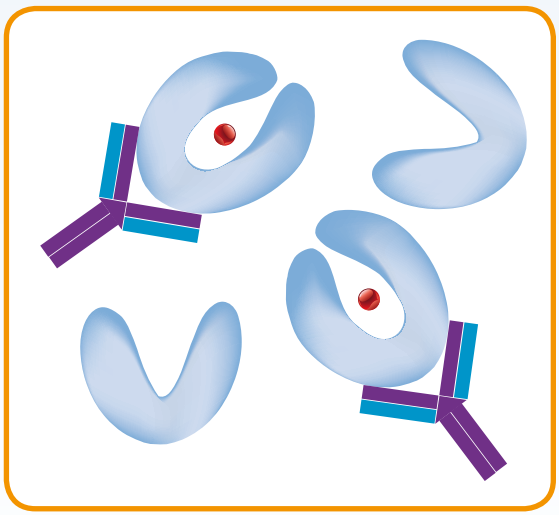
Recombinant Fusion Protein **(RFP)**



Specific murine monoclonal antibody ***(MAB)*** which only recognizes the RFP Complex



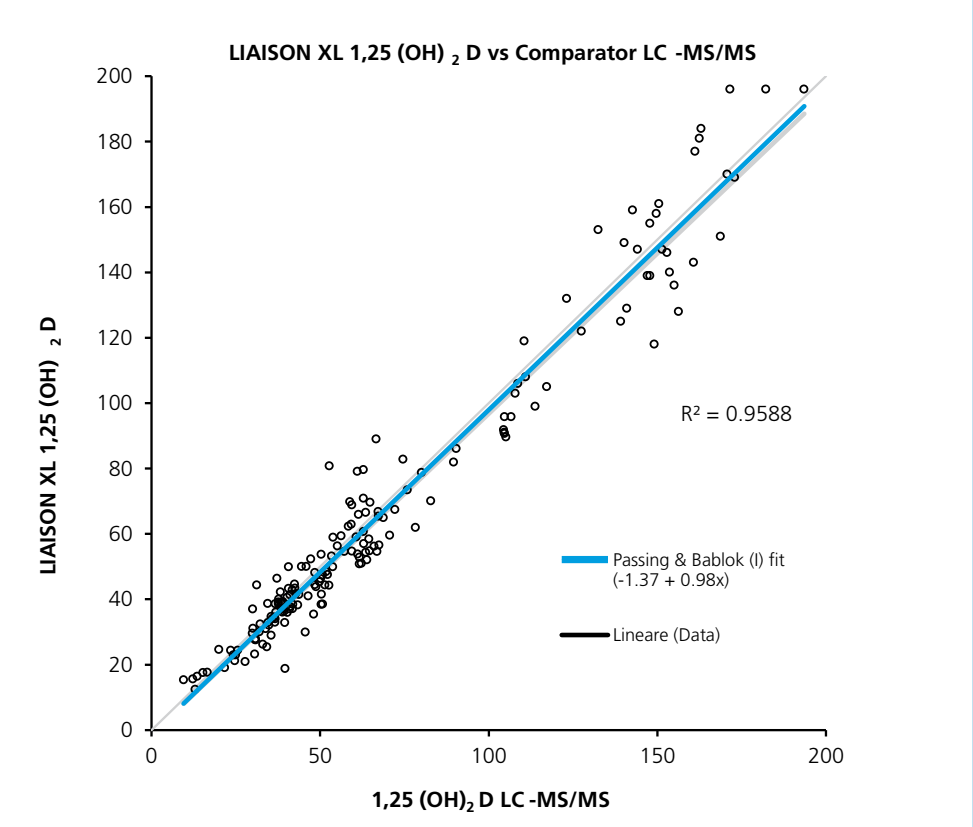
RFP changes conformation after capturing $1,25(OH)_2$D and forms the ***RFP Complex***



RFP Complex is selectively recognized by the MAB

Specific performance characteristics

PATIENT CORRELATION/METHOD COMPARISON
A total of 173 samples spanning the assay range were tested by the LIAISON® XL 1,25 Dihydroxyvitamin D and LC-MS/MS comparator assay following CLSI EP9-A3. The study yielded the following Passing & Bablok regression analysis: LIAISON® XL 1,25 Dihydroxyvitamin D = 0.9811x – 1.37; R^2 = 0.9588



Precision

Two lots of kit controls and 6 serum samples spanning the range of the assay were tested twice per day in duplicate, over twenty days using 2 reagent lots on 2 XL Analyzers at DiaSorin Inc. The testing was performed according to CLSI EP5-A2.

SAMPLE ID	N	MEAN $1,25(OH)_2$ D (pg/mL)	BETWEEN-LOT		TOTAL (ACROSS LOTS)	
			SD	%CV	SD	%CV
Kit Control 1	160	30.9	0.84	2.7%	1.16	3.8%
Kit Control 2	160	122.9	6.09	5.0%	4.36	3.6%
Prec Serum 1	160	23.3	0.05	0.2%	1.53	6.6%
Prec Serum 2	160	38.9	0.63	1.6%	2.20	5.7%
Prec Serum 3	160	52.7	0.64	1.2%	2.65	5.0%
Prec Serum 4	160	76.0	1.33	1.7%	3.13	4.1%
Prec Serum 5	160	137.4	1.91	1.4%	6.55	4.8%
Prec Serum 6	160	193.4	5.53	2.9%	11.34	5.9%

Sample Equivalence - Linearity

Fifty-one (51) matched patient sets of serum, SST serum, EDTA plasma, and Lithium Heparin plasma samples were tested to determine if these sample types provide equivalent results on the LIAISON® XL 1,25 Dihydroxyvitamin D assay. The results were analyzed by regression of Observed $1,25(OH)_2$ D Concentration (serum, SST Serum, EDTA plasma or Lithium Heparin plasma) versus expected $1,25(OH)_2$ D Concentration (serum).

The resulting equations for each sample type are:

Serum: Observed 1,25(OH)2 D = 1.014x - 1.936; R^2 = 0.9829

SST Serum: Observed 1,25(OH)2 D = 1.011x - 0.285; R^2 = 0.9908

EDTA plasma: Observed 1,25(OH)2 D = 1.010x + 0.321; R^2 = 0.9975

Lithium Heparin plasma: Observed 1,25(OH)2 D = 1.000x + 0.100; R^2 = 0.9957

Expected Values

It is recommended that each laboratory establishes its own range of expected values.

To assess the expected reference range for the LIAISON® XL 1,25 Dihydroxyvitamin D a study was performed with samples from 123 apparently healthy adults aged 21-75 years of age from mixed ethnic backgrounds (48% dark-skinned and 52% light-skinned). Samples were collected in the winter (48.8%) and summer (51.2%) from subjects with normal Total Calcium, TSH and PTH values from the northern, central, and southern regions of the U.S.

Based on the 95% Reference Interval, the following values were established following CLSI guideline EP28-A3C.

U.S. SUBJECTS	MEDIAN $1,25(OH)_2$ D	OBSERVED RANGE 2.5^{TH} TO 97.5^{TH} PERCENTILE
n = 123	47.8 pg/mL	19.9 – 79.3 pg/mL

- **First fully automated, extraction free**
- **First result in just 65 minutes**
- **Low sample volume (75 µL)**
- **More test from the same patient tube (eg 25-OH Vitamin D, PTH)**

Available only on LIAISON® XL

The LIAISON® XL assay removes the necessity of manual sample extraction, by performing all assay steps on-board the analyser.

Time to first result within 65 minutes.

Bone & Mineral

LIAISON® XL 1,25 Dihydroxyvitamin D

The DiaSorin LIAISON® XL 1,25 Dihydroxyvitamin D is an *in vitro* chemiluminescent immunoassay (CLIA) intended for the quantitative determination of 1,25 Dihydroxyvitamin D in serum, EDTA and Lithium Heparin plasma.

LIAISON® XL 1,25 Dihydroxyvitamin D (code 310980)

LIAISON® XL 1,25 Dihydroxyvitamin D Controls (code 310984)

LIAISON® XL 1,25 Dihydroxyvitamin D Specimen Diluent (code 310982)

The LIAISON® Bone & Mineral panel also includes:

LIAISON® 25 OH Vitamin D TOTAL Assay (Code 310600)
LIAISON® 1-84 PTH (Code 310630)
LIAISON® N-TACT® PTH Gen II (Code 317910)
LIAISON® BAP OSTASE® (Code 310970)
LIAISON® Osteocalcin (Code 310950)

AVAILABLE ONLY ON LIAISON® XL

Product availability subject to required regulatory approval

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DiaSorin

The Diagnostic Specialist

DiaSorin S.p.A.
Via Crescentino, snc
13040 Saluggia (VC) Italy
Tel. +39 0161 487 526/947
Fax +39 0161 487 670
www.diasorin.com
info@diasorin.it