CPAL
Central **P**ennsylvania **A**lliance **L**aboratory

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1,25 Dihydroxyvitamin D
- New Assay -

Contact: Steph Frey, 717.812.4768
Operations Manager, Clinical Pathology, CPAL

Dr. Jennifer Thebo, 717.851.3210
Director of Technical Operations and Scientific Affairs, CPAL

Ordering Information and Suggested Codes:

Mnemonics:	1,25 Dihydroxyvitamin D	VIT D Group
Test Name:	Vitamin D 1,25 dihydroxy	VIT D Group
Test Number:	1750210	1750190
Includes:		Vitamin D (Total) -1750200 Vitamin D 1,25 dihydroxy-1750210
Specimen:	Serum, EDTA or Lithium Heparin Plasma Refrigerated for 14 days	Serum only Refrigerated for 5 days
LOINC Codes	62290-2	35365-6 and 62290-2
CPT Codes	82652	82306 and 82652

Effective Date: Testing offered beginning on Monday, March 28, 2016.

Performed: Wednesday/Thursday dayshift

Note for testing schedule: To start, testing will be limited to 2 consecutive days due to the short expiration date of a limiting reagent. Once specimen volumes increase, we will look to increase the frequency of testing.

Reference Range:

Age	Previous Range (Quest)	New Range (CPAL)
<1 year of age	No reference range established	No reference range established
1 – 9 years	31.0 – 87.0 pg/mL	31.0 – 87.0 pg/mL
10 – 13 years	30.0 – 83.0 pg/mL	30.0 – 83.0 pg/mL
14 – 17 years	19.0 – 83.0 pg/mL	19.0 – 83.0 pg/mL
Adult	18.0 – 72.0 pg/mL	19.9 – 79.3 pg/mL

Background:

1,25-Dihydroxyvitamin D is the most potent vitamin D metabolite. It stimulates calcium absorption in the intestine and its production is tightly regulated through concentrations of serum calcium, phosphorus, and parathyroid hormone.

1,25-Dihydroxy vitamin D levels may be high in primary hyperparathyroidism and in physiologic hyperparathyroidism secondary to low calcium or vitamin D intake. Some patients with granulomatous diseases (eg, sarcoidosis) and malignancies containing nonregulated 1-alpha hydroxylase in the lesion may have elevated

1,25-dihydroxy vitamin D levels and hypercalcemia. 1,25-Dihydroxy vitamin D levels are decreased in hypoparathyroidism and in chronic renal failure.

The clinical practice guidelines such as the Kidney Disease Outcomes Quality Initiatives (KDOQI), and the Kidney Disease: Improving Global Outcomes (KDIGO) recommend activated vitamin D therapeutic regimens for chronic kidney disease (CKD) patients. Consequently, the measurement of 1,25 $(OH)_2$ D is rapidly becoming an efficient tool in the research of diseases and conditions that affect the normal metabolism of phosphorus and calcium.

Note that, while 1,25-(OH)2-D is the most active form of vitamin D, it is not appropriate for general screening to determine vitamin D status. In the absence of disease affecting vitamin D uptake and metabolism, 25-OH-D is the best tool for assessing vitamin D status. Test code 1750200 Vitamin D (Total).

Principle of Test:

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 ($1,25(OH)_2D$) in serum, EDTA and Lithium Heparin plasma. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions in adult populations.

Validation Data:

Precision:

For within run precision, two levels of control were run ten times each, within the same run. For between run precision, two levels of control were run five times each on two different days. The %CVs fall within the Manufacturer's claim of <4.3% for level 1 and <3.5% for level 3. (Table 1)

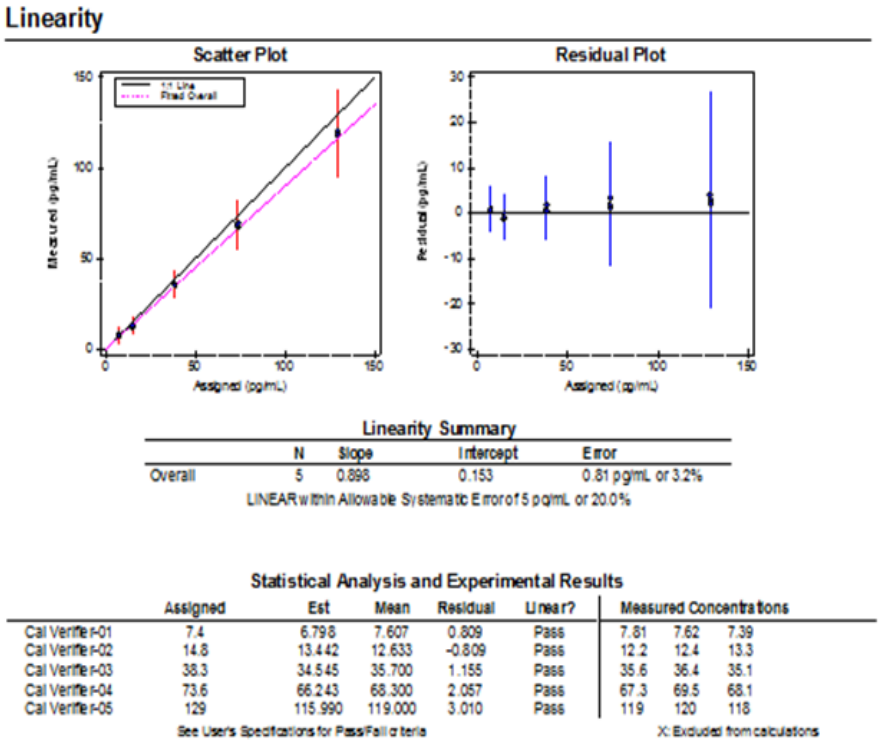
Table 1: Precision

Test	Within Run Precision				Between Run Precision				Accept?
	Mean Lev 1	CV	Mean Lev 3	CV	Mean Lev 1	CV	Mean Lev 3	CV	
1,25 Dihydroxyvitamin D	26.47	2.56%	107.30	1.81%	25.66	4.03%	104.96	3.22%	Yes

Linearity:

To verify the linearity of the assay, DiaSorin's Liaison XL 1,25 Dihydroxyvitamin D Calibration Verifiers were run in triplicate. To verify the lower end of linearity, Cal Verifier was diluted with Liaison XL 1,25 Dihydroxyvitamin D Diluent at 1:2. (Figure 1)

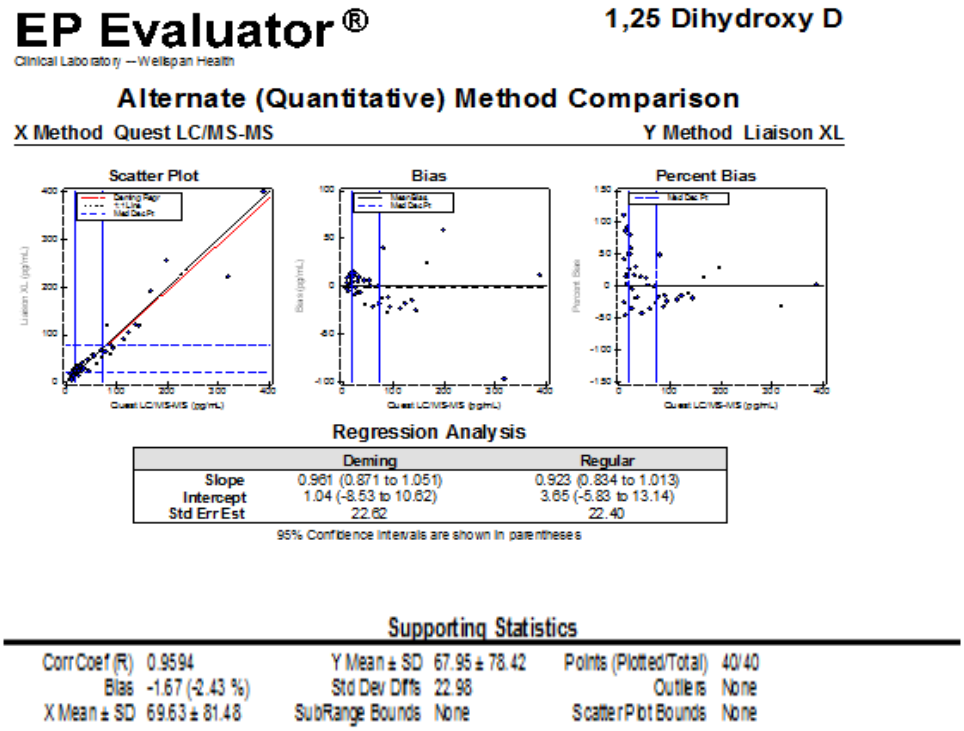
Figure 1: Linearity



Method Comparison:

Forty specimens were split and processed utilizing Liaison XL 1,25 Dihydroxyvitamin D assay versus results from Quest Diagnostics. (Figure 2) The manufacturer's suggested reference range for adults was verified by medical decision point analysis.

Figure 2: Method Comparison



Limitations:

1. Note that 1, 25 dihydroxyvitamin D is not the preferred screening test to assess vitamin D status. 25 hydroxyvitamin D more accurately reflects the body's vitamin D stores and is therefore the preferred test for initial screening. 1, 25 dihydroxyvitamin D may be useful in evaluating renal disease, bone disorders, and other diseases such as sarcoidosis.
2. Bacterial contamination of samples or repeated freeze-thaw cycles may affect the test results.
3. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed.
4. Assay results should be utilized in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.
5. Do not heat inactivate serum or plasma.
6. The Liaison XL 1, 25 Dihydroxyvitamin D has been shown to cross-react with Zemplar (paricalcitol), an active form of Vitamin D.

References:

1. DiaSorin Liaison 1,25 Dihydroxyvitamin D Assay package insert, 08/15.
2. DiaSorin Liaison 1,25 Dihydroxyvitamin D Control Set insert, 08/15.
3. DiaSorin Liaison 1,25 Dihydroxyvitamin D Diluent insert, 08/15.