CPAL

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

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25-OH Vitamin D
-Testing Platform Change-

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Ordering Information and Suggested Codes:

Mnemonic:	Vit D
Test Name:	Vitamin D Total (25 OH Vit D)
Test Number:	1750200
Specimen:	Serum
LOINC Codes	35365-6
CPT Code	82306

Effective Date: October 1, 2018

Performed: Monday through Saturday

Reference Range:

Vitamin D Status	Previous Range	New Range
Deficiency	<10 ng/mL	<10 ng/mL
Insufficiency	10-30 ng/mL	10-30 ng/mL
Sufficiency	30-100 ng/mL	30-100 ng/mL
Toxicity	>100 ng/mL	>100 ng/mL

Introduction:
Vitamin D is a fat-soluble steroid prohormone mainly produced photochemically in the skin from 7-dehydrocholesterol. Two forms of vitamin D are biologically relevant - vitamin D3 (Cholecalciferol) and vitamin D2 (Ergocalciferol). Epidemiological studies have shown a high global prevalence of vitamin D insufficiency and deficiency. Risk factors for vitamin D deficiency include low sun exposure, malnutrition, some malabsorption syndromes, and liver or kidney diseases. The measurement of vitamin D status provides opportunities for preventive and therapeutic interventions. Vitamin D deficiency is a cause of secondary hyperparathyroidism and diseases resulting in impaired bone metabolism (like rickets, osteoporosis, osteomalacia).

Principle of Test:
The Architect 25-OH Vitamin D assay is a quantitative delay one-step competitive immunoassay to determine the presence of vitamin D in human serum and plasma using Chemiluminescent Microparticle Immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemiflex. The Architect 25-OH Vitamin D assay is standardized against NIST SRM 2972 (National Institute of Standards & Technology Standard Reference Material 2972).

Specimen:
Human serum and plasma (Dipotassium EDTA, Tripotassium EDTA, Sodium heparin, Lithium heparin powder, Plasma separator tubes-lithium heparin gel) may be used for the Architect Vitamin D assay. Specimens may be stored for up to 72 hours at room temperature or up to 12 days refrigerated at 2-8°C.

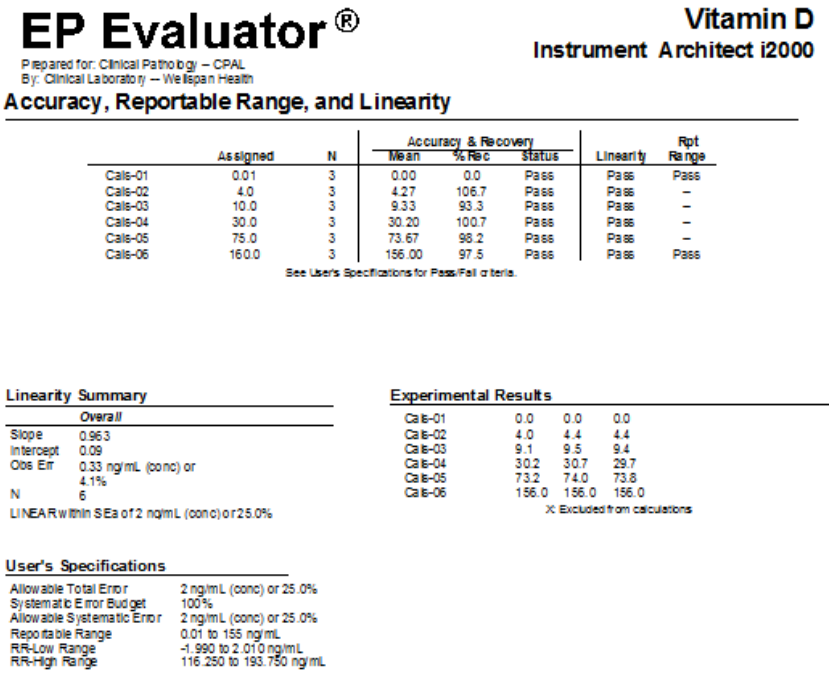
Validation Studies:
Precision:
Two levels of control were run ten times each, within the same run and on two different days. The %CVs fall within the Manufacturer's claim of ≤ 10.0% for both within run precision and between run precision. (Table 1)

Table 1: Precision

Test	Within Run Precision				Between Run Precision				Accept
	Level 1 Mean	%CV	Level 3 Mean	%CV	Level 1 Mean	%CV	Level 3 Mean	%CV	
Vitamin D	8.50	3.55	34.1	2.23	8.66	4.10	34.4	2.07	Yes

Linearity:
To verify the AMR and linearity of the assay, standardized specimens were run in triplicate. The results were entered into EP Evaluator. Please see the EP Evaluator results below (Figure 1). The calculated slope is 0.963 with an intercept of 0.09 and an observed error of 0.33 ng/mL or 4.1 %. The assay is linear within Allowable Systematic Error of 2 ng/mL or 25.0%. The linearity validation is acceptable and the AMR of the assay verified.

Figure 1: Linearity



EP Evaluator®

Vitamin D
Instrument Architect i2000

Prepared for: Clinical Pathology – CPAL
By: Clinical Laboratory – Wellspan Health

Accuracy, Reportable Range, and Linearity

	Assigned	N	Accuracy & Recovery Mean	% Rec	Status	Linearity	Rpt Range
Cals-01	0.01	3	0.00	0.0	Pass	Pass	Pass
Cals-02	4.0	3	4.27	106.7	Pass	Pass	–
Cals-03	10.0	3	9.33	93.3	Pass	Pass	–
Cals-04	30.0	3	30.20	100.7	Pass	Pass	–
Cals-05	75.0	3	73.67	98.2	Pass	Pass	–
Cals-06	160.0	3	156.00	97.5	Pass	Pass	Pass

See User's Specifications for Pass/Fail criteria.

Linearity Summary

	Overall
Slope	0.963
Intercept	0.09
Obs Err	0.33 ng/mL (conc) or 4.1%
N	6

LINEAR within SEa of 2 ng/mL (conc) or 25.0%

Experimental Results

Cals-01	0.0	0.0	0.0
Cals-02	4.0	4.4	4.4
Cals-03	9.1	9.5	9.4
Cals-04	30.2	30.7	29.7
Cals-05	73.2	74.0	73.8
Cals-06	156.0	156.0	156.0

X Excluded from calculations

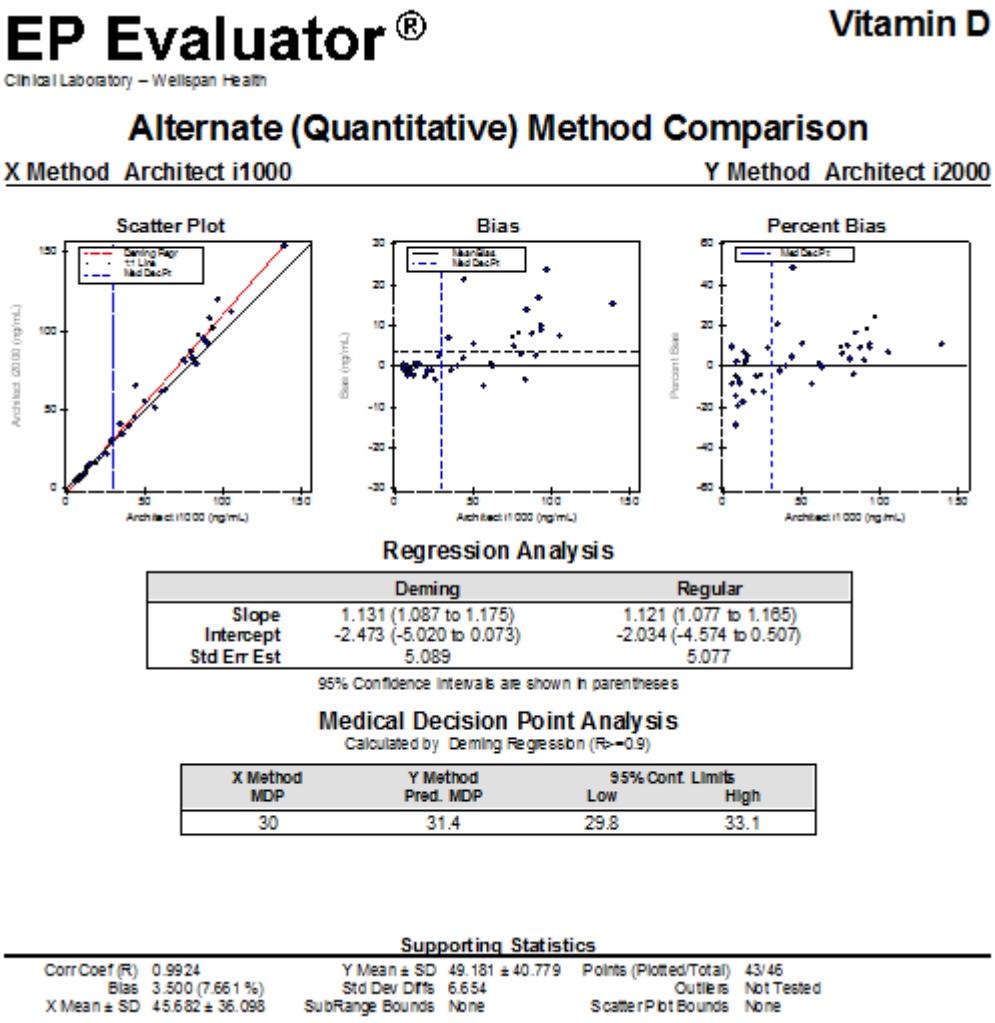
User's Specifications

Allowable Total Error	2 ng/mL (conc) or 25.0%
Systematic Error Budget	100%
Allowable Systematic Error	2 ng/mL (conc) or 25.0%
Reportable Range	0.01 to 155 ng/mL
RR-Low Range	-1.990 to 2.010 ng/mL
RR-High Range	116.250 to 193.750 ng/mL

Method Comparison:

Forty-six specimens were split and processed utilizing DiaSorin's Liaison XL and Abbott's Architect *i*2000 (Figure 2). Quantitative analysis yielded a correlation coefficient (R) of 0.9924 with a slope of 1.131 and an intercept of -2.473. Overall bias for the Liaison XL versus Architect i2000 was 7.661%.

Figure 2: Method Comparison



References:

1. Architect 25-OH Vitamin D package insert; August 2016.