CPAL

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

Technical Bulletin

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Hepatitis B Surface Antibody -Assay Restandardization–

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Ordering Information and Suggested Codes:

Mnemonic:	HBSAB QNT	.HEPPOSTVAC	EHBSAB
Test Name:	Hepatitis B: HBsAb Quant (Total)	Hepatitis B: Post Hepatitis B Vaccination (LGH)	Hbsab Quant (Emp LGH)
Test Number:	1750042	1750043	1750039
Specimen:	Serum	Serum	Serum
LOINC Codes	5193-8	5193-8	5193-8
CPT Codes	86706	86706	86706

Effective Date: April 30, 2018

Performed: Monday through Saturday

Introduction:
Abbott Diagnostics has enhanced their Hepatitis B Surface Antibody (AUSAB) assay as part of their ongoing commitment to product improvements. The Architect AUSAB assay has been re-standardized to the WHO 2nd International Reference Preparation, 2008 (Code 07/164) instead of the WHO 1st International Reference Preparation, 1977 (Code W1042). An upward shift of approximately 6% - 14% may be observed with patient specimens upon implementation of the newly re-standardized assay. Abbott conducted studies on negative and positive patient populations. The studies demonstrated that the performance of the 1st WHO standardized and 2nd WHO standardized assay is in agreement.

Validation Studies:
Precision:
Two levels of control were run ten times each, within the same run and on two different days. The manufacturer's claim for within run precision of ≤ 10 % for specimens with a positive result was met. Abbott does not publish criteria for specimens with a result of negative. (Table 1)

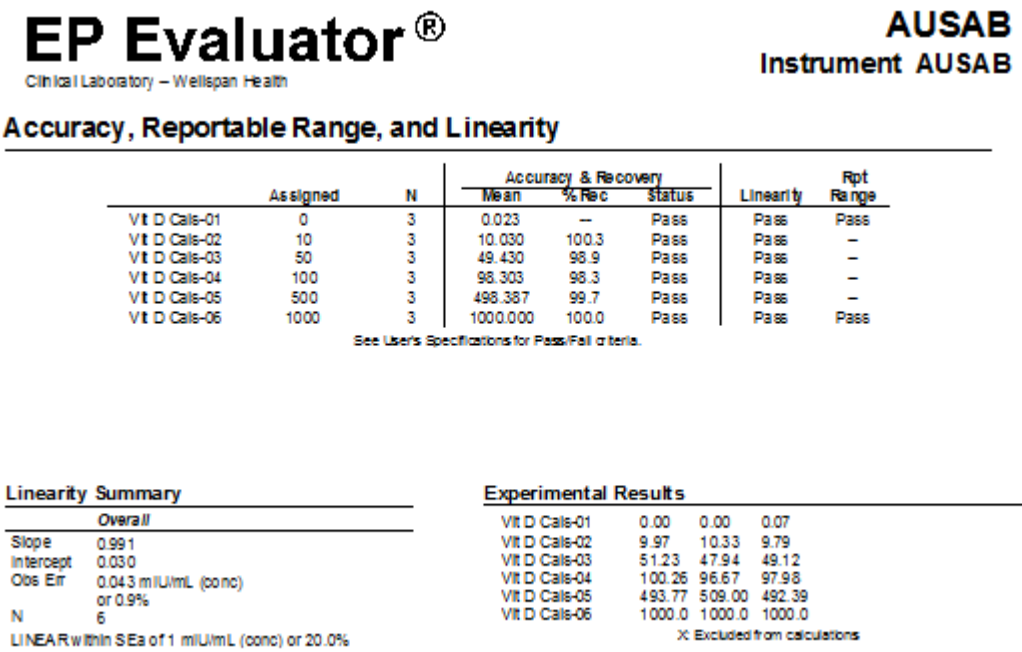
Table 1: Precision

Test	Within Run Precision				Between Run Precision				Accept
	Neg Pool Mean	%CV	Pos Pool Mean	%CV	Neg Pool Mean	%CV	Pos Pool Mean	%CV	
AUSAB	2.70	10.46	896.56	2.20	2.70	10.35	892.73	1.84	Yes

AMR and Linearity:

To verify the AMR and linearity of the assay, AUSAB calibrators of a different lot than those used to calibrate the assay, were run in triplicate. The results were entered into EP Evaluator. Please see the EP Evaluator results below (Figure 1). The calculated slope is 0.991 with an intercept of 0.030 and an observed error of 0.043 mIU/mL or 0.9 %. The assay is linear within Allowable Systematic Error of 1 mIU/mL or 20.0%. The linearity validation is acceptable and the AMR of the assay verified.

Figure 1: AMR and Linearity



EP Evaluator®

Clinical Laboratory – Wellspan Health

AUSAB

Instrument AUSAB

Accuracy, Reportable Range, and Linearity

	Assigned	N	Accuracy & Recovery Mean	%Rec	Status	Linearity	Rpt Range
Vit D Cals-01	0	3	0.023	--	Pass	Pass	Pass
Vit D Cals-02	10	3	10.030	100.3	Pass	Pass	--
Vit D Cals-03	50	3	49.430	98.9	Pass	Pass	--
Vit D Cals-04	100	3	98.303	98.3	Pass	Pass	--
Vit D Cals-05	500	3	498.387	99.7	Pass	Pass	--
Vit D Cals-06	1000	3	1000.000	100.0	Pass	Pass	Pass

See User's Specifications for Pass/Fail criteria.

Linearity Summary

	Overall
Slope	0.991
Intercept	0.030
Obs Err	0.043 mIU/mL (conc) or 0.9%
N	6

LINEAR within SEa of 1 mIU/mL (conc) or 20.0%

Experimental Results

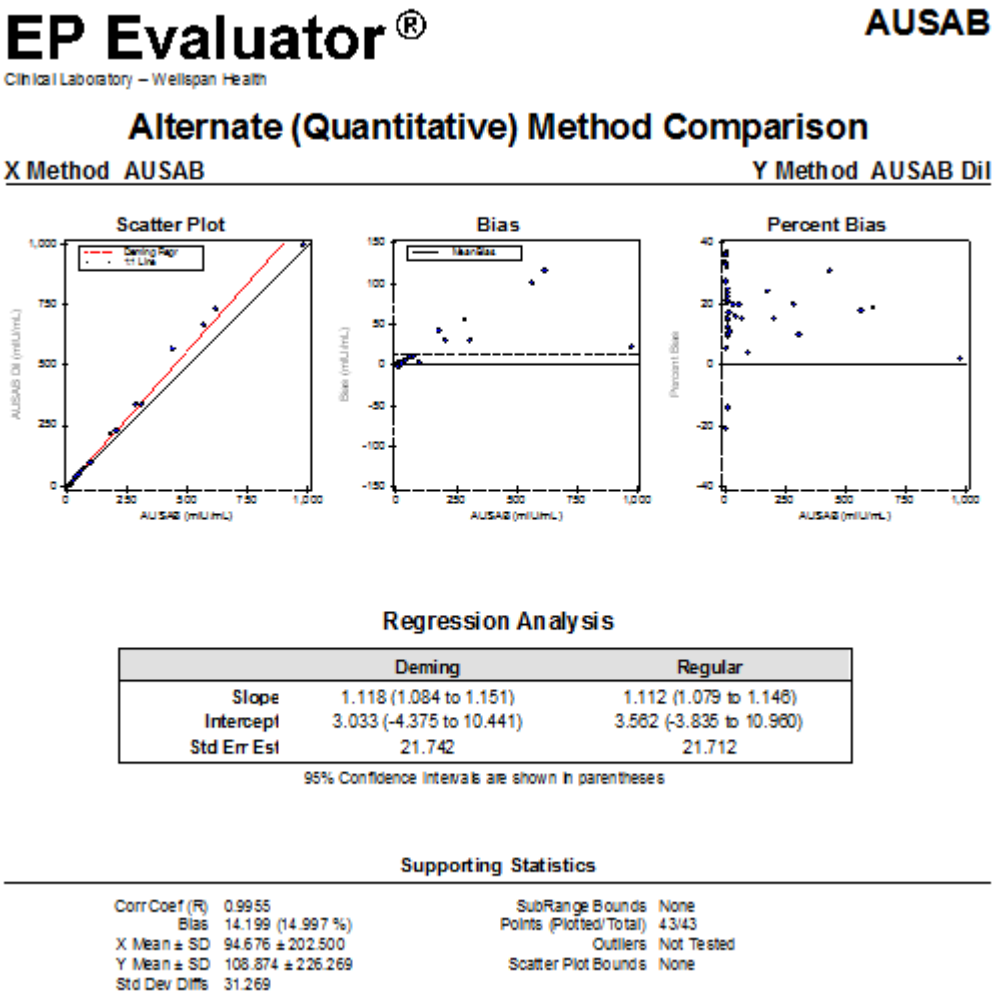
Vit D Cals-01	0.00	0.00	0.07
Vit D Cals-02	9.97	10.33	9.79
Vit D Cals-03	51.23	47.94	49.12
Vit D Cals-04	100.26	96.67	97.98
Vit D Cals-05	493.77	509.00	492.39
Vit D Cals-06	1000.0	1000.0	1000.0

X: Excluded from calculations

Method Comparison:

Forty-three specimens were split and processed utilizing the current Architect AUSAB and the 2nd WHO standardized Architect AUSAB assay. Quantitative analysis yielded a correlation coefficient (R) of 0.9955 with a slope of 1.118 and an intercept of 3.033 (Figure 2). Overall bias for the current assay vs the newly standardized assay was 14.997%.

Figure 2: Method Comparison



References:

1. Product Information Letter, Abbott Diagnostics, January 2018.
2. Architect AUSAB IFU, Abbott Diagnostics, March 2017.