

Adaptation of Plasma Protein Assays to a New Analyzer: The Dimension Vista™ System

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Introduction

The new Dimension Vista™ system is designed as a consolidated high throughput analyzer for the medium to large clinical laboratory, offering a broad menu and many ease-of-use features to optimize workflow. Multiple independent detection modules are incorporated including a photometer for traditional clinical chemistry assays, a LOCI™ detector for high-sensitivity immunoassays, a nephelometer for routine and specialty plasma protein assays, and integrated multi-sensor technology for electrolytes.



Dimension Vista™ 3000T System

The adaptation of plasma proteins to this new analyzer has been performed with the goal of demonstrating equivalent performance to that of the BN ProSpec® system.

The menu list will incorporate all major plasma protein assays. This poster focuses on the performance results of the following 11 assays*:

CRP, hsCRP
MALB (Microalbumin, Albumin in urine)
IgG, IgA, IgM
C3, C4
PREALB (Prealbumin)
RF (Rheumatoid Factors)
ASL (Antistreptolysin-O)

The reagents as well as the processing parameters were optimized in order to maximize sensitivity and assay range, provide security against antigen excess and minimize time to first result. The assays incorporate new ease-of-use features such as auto-calibration, automatic predilution and reflex testing, positive identification of calibrators, controls and reagents, and on-board storage of reagents, calibrators, and controls.

Materials and Methods

The assay adaptation and performance verification were conducted at Dade Behring using Dimension Vista™ systems and BN ProSpec® systems were the comparative device. All reagents, calibrators and controls were from Dade Behring Marburg GmbH. Studies for imprecision were executed according to NCCLS guideline EP-15A. Method comparisons were evaluated by regression analysis according to Passing and Bablok. Assay linearity was verified by serial dilutions across the measuring range. Results obtained were compared by linear regression analysis to the expected values. Sensitivity was assessed by verification that the signal of the lowest calibration points exceeds the signal of the blank measurement by at least 2 SD in a 12-fold repetition.

*Product under development – Not available for sale.

Results

Measuring range

Measuring ranges have been optimized for the new system per the following table.

Assay*	Range
CRP	3.0-190 mg/L
hsCRP	0.15-9.5 mg/L
MALB	11-340 mg/L
IgG	1.2-37 g/L
IgA	0.25-7.5 g/L
IgM	0.2-6.4 g/L
C3	0.16-4.1 g/L
C4	0.06-1.9 g/L
PREALB	0.02-0.6 g/L
RF	10-600 IU/mL
ASL	50-1600 IU/mL

Sensitivity

Sensitivity studies demonstrate that there is a clear differentiation of the lowest calibration point to the blank.

Antigen Excess Security

Studies have shown the security against high-dose hook effects. For IgG, a sample with a concentration of 70 g/L was used to check this effect. This sample showed a signal above that of the highest calibrator and was quantitated correctly in reflex testing. For IgM and Microalbumin, a pre-reaction protocol is utilized to check for antigen excess. In these assays, the reaction is initiated with a reduced amount of sample. The remainder of the sample volume is added in the main reaction and the assay cycle repeated without adding any more reagent.

Method Comparisons

Method comparisons were performed against the BN ProSpec® system using serum samples, except MALB which used urine samples. An additional 50 heparinized plasma samples also were processed by the IgG assay. The results from linear regression analysis of the data according to Passing and Bablok (P-B) are summarized in the table below. Selected method comparison plots are shown in Figures 1 to 4. The results showed excellent agreement between systems for the assays evaluated.

Assay*	Slope	Y-Intercept	Units	r	N
CRP	1.00	-0.01	mg/L	0.999	41
hsCRP	1.01	0.18	mg/L	0.995	28
MALB	1.03	0.39	mg/L	0.995	17
IgG	1.00	0.49	g/L	0.992	98
IgA	1.03	-0.11	g/L	0.997	32
IgM	1.12	-0.08	g/L	0.984	61
C3	1.06	-0.14	g/L	0.963	30
C4	0.96	0.01	g/L	0.998	34
PREALB	0.97	0.00	g/L	0.987	29
RF	1.02	2.31	IU/mL	0.996	23
ASL	1.14	-2.95	IU/mL	0.999	26

Results - con.

Figure 1: IgG
P-B Regression Statistics
Slope: 1.00
Y-int: 0.49
r: 0.992
N: 98

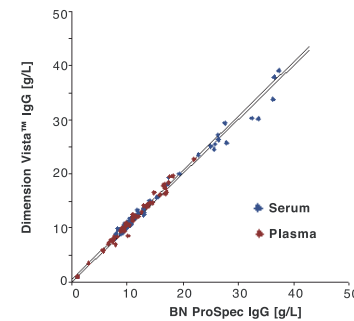


Figure 2: CRP
P-B Regression Statistics
Slope: 1.00
Y-int: -0.01
r: 0.999
N: 41

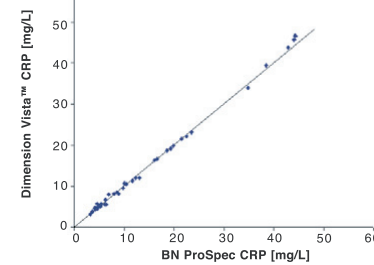


Figure 3: MALB
P-B Regression Statistics
Slope: 1.03
Y-int: 0.39
r: 0.995
N: 17

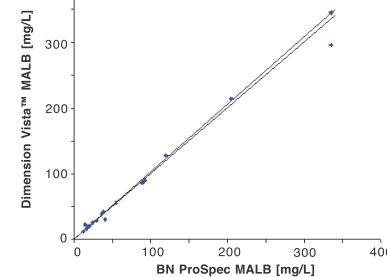
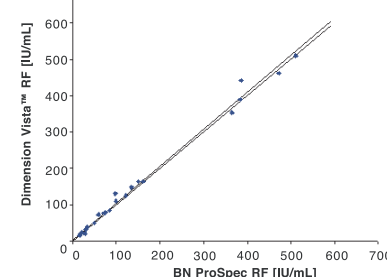


Figure 4: RF
P-B Regression Statistics
Slope: 1.02
Y-int: 2.31
r: 0.996
N: 29

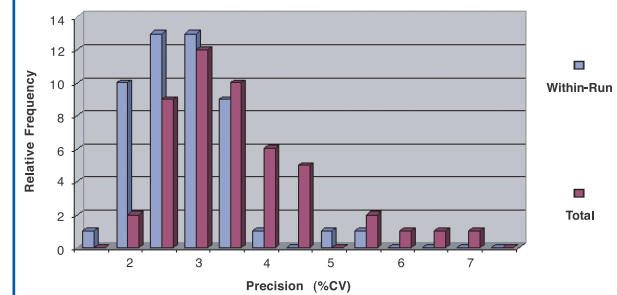


Results - con.

Precision Studies

Studies were performed to assess within-run and total precision following the protocol of CLSI/NCCLS EP 15-A. The results from all methods are summarized in the cumulative histogram shown in Figure 5. The median within-run CV is 2.7% (95% confidence interval: 1.7-3.6%), with a median total CV of 3.1% (95% confidence interval: 2.1-5.7%).

Figure 5: Method Imprecision Histogram



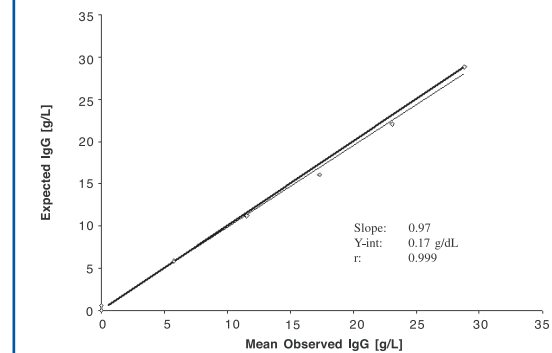
Recovery

Recovery of controls was within ± 10% in all measurements.

Dilution Linearity

Linearity of assays was demonstrated by serially diluting a sample with high analyte concentration and comparing the mean observed results to theoretical values by linear regression analysis. Linearity was demonstrated for all methods. Figure 6 shows an example data set for IgG.

Figure 6: IgG Dilution Linearity

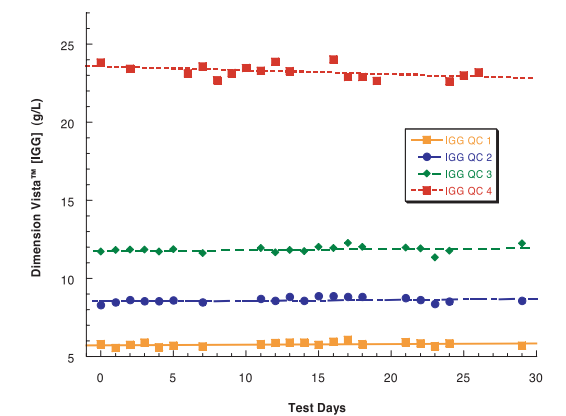


Results - con.

Calibration Stability

Calibration stability was assessed for IgG as a pilot assay. Four levels of quality control products were run each testing day for a month. Linear regression analysis showed no significant drift (< 5%) over the testing interval for any sample, as shown in Figure 7.

Figure 7: IgG Calibration Stability



Conclusions

The initial evaluation of these plasma protein assays on the Dimension Vista™ system demonstrated equivalent performance to that seen with the BN ProSpec® system.

The Dimension Vista™ system will meet the needs of laboratories and enable them to consolidate the bulk of their assay portfolio—including plasma protein assays—on one analyzer.

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