

Adaptation of Plasma Protein Assays to a New High-Volume Multi-Detector Analyzer: the Dimension Vista™ System

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The Dimension VISTA™ system* is designed as a consolidated high throughput analyzer offering a broad menu and many ease-of-use features to optimize workflow. Multiple independent detection modules enable the processing of routine and specialty plasma protein assays together with clinical chemistry assays, immunoassays, and electrolytes—all from the same sample tube. The plasma protein assays for the Dimension Vista™ system are based upon the nephelometric detector, reagents, and measuring principles of the well-established Dade Behring BN ProSpec® system.

Existing plasma protein reagents and processing parameters were optimized for the Dimension VISTA™ system to maximize sensitivity and assay range, provide security against antigen excess conditions, and minimize time to first results. The assays also incorporate new ease-of-use system features such as automatic calibration and sample dilution; positive identification of calibrators and controls; and onboard storage of liquid reagents, calibrators and controls. Samples can be serum or heparinized plasma, as well as CSF or urine as appropriate for the assay (e.g., Microalbumin for albumin in urine).

Initial plasma protein assays for the system include: CRP, high sensitivity CRP (hsCRP), Microalbumin (MALB), IgG, IgA, IgM, C3, C4, RF, and ASL. The following performance data demonstrate initial measuring range, within-run and total precision (based on the 5 day protocol of NCCLS EP-15), and method comparison versus the BN ProSpec® system (data analyzed by Passing-Bablok regression). The precision ranges refer to results across multiple levels of controls, where applicable. Time to first result is 10 minutes for all assays, except MALB and IgM where it is 21 minutes due to a pre-reaction check for potential antigen excess.

Assay	Initial Measuring Range	Reproducibility (%CV)		Slope	Method Comparison		
		Within-Run	Total		Y-int	r	N
CRP	2.8 - 180 mg/L	1.7 – 2.9 %	2.6 – 3.0 %	1.00	-0.01	0.999	41
hsCRP	0.14 - 8.8 mg/L	2.7 – 3.3 %	2.7 – 4.4 %	1.01	0.18	0.995	28
MALB	11 - 340 mg/L	4.6 %	5.9 %	1.03	0.39	0.995	17
IgG	1.2 - 37 g/L	1.8 – 2.9 %	1.9 – 3.3 %	1.00	0.63	0.996	30
IgA	0.25 - 8.0 g/L	1.3 – 5.2 %	2.2 – 6.5 %	1.03	-0.11	0.997	32
IgM	0.2 - 6.4 g/L	3.0 – 3.2 %	3.0 – 4.2 %	1.12	-0.08	0.984	61
C3	0.12 - 4.1 g/L	2.4 – 3.2 %	3.9 – 4.2 %	1.06	-0.14	0.963	30
C4	0.06 - 1.9 g/L	4.5 – 5.7 %	6.0 – 8.2 %	0.96	0.01	0.998	34
RF	10 - 600 IU/mL	2.2 – 2.5 %	2.3 – 3.0 %	1.02	2.31	0.996	23
ASL	50 - 1600 IU/mL	2.4 – 2.6 %	3.1 – 3.4 %	1.14	-2.95	0.999	26

We conclude that the Dimension Vista™ system demonstrates good performance for plasma protein assays which should meet the needs of the laboratories.