ALBUMIN BCG (2-8°C)

(BROMOCRESOL GREEN)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRALB2	6x60ml / 1x5ml
MPRALB3	5x100ml / 1x5ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
Albumin BCG method is intended for the quantitative determination of albumin in human serum or plasma on chemistry analysers.
The product is intended for use by qualified laboratory personnel only.

Clinical Significance:
Albumin has two main functions: to maintain water balance in serum and plasma, and to transport a variety of ligands, for example calcium, bilirubin and hormones.
Levels below the normal range (hypoalbuminaemia) are the most clinically significant associated with conditions such as malnutrition, liver disease, kidney disease and intestinal disease. Levels above the normal range (hyperalbuminaemia) have little diagnostic significance although they may be an indication of dehydration.

Test Principle:
Serum Albumin binds with the Bromocresol Green indicator in an acidic medium to form a blue-green BCG complex. The colour intensity of this blue green complex is directly proportional to the concentration of albumin in the sample.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
BCG REAGENT	Bromocresol Green	0.12mmol/L pH 4.2
ALBUMIN STANDARD	Bovine Serum Albumin	5.0 g/dl (NIST SRM 927a)

Reagent Preparation and Stability:
R1: Liquid, ready to use
Standard: Liquid, ready to use
R1 and Standard are stable to the expiry date when stored unopened at 2 - 8°C. Avoid exposure to direct sunlight.
Exercise the normal precautions associated with the handling of laboratory reagents and dispose of carefully according to local guidelines.

Sample Collection, Preparation and Stability:
Collect serum and heparin or EDTA plasma by standard venepuncture technique. Albumin is stable in the sample for up to 4 weeks when stored at 2 - 8°C, or up to one week at 15 - 25°C. For longer storage store at -20°C.

Assay Procedure:

WAVELENGTH	630nm (600-650nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample (µl)	-	-	5
Standard (µl)	-	5	-
Reagent (µl)	1000	1000	1000
Mix and incubate 5 minutes at assay temperature. Read absorbance of Sample/Standard against the Reagent Blank.			

Calculation:
Albumin Concentration (g/dl) = $\frac{\Delta Abs\ Sample}{\Delta Abs\ Standard}$ x Concentration of Standard

Performance Characteristics:

Measuring range:
0.2 g/dl – 6.0 g/dl (2g/l – 60 g/l)
Dilute samples with higher concentrations than 6.0 g/dl (60g/l) using Normal saline 1+1 and rerun the assay. Multiply the result by the dilution factor (for 1+1 dilution, the dilution factor is 2)

Analytical Sensitivity: (Lowest detection limit):
0.2 g/dl (2 g/l)

Intra-Assay Precision:

Sample	Mean (g/dl)	SD (g/dl)	CV %
Pool 1	5.00	0.02	0.47
Pool 2	3.71	0.02	0.55

Inter-Assay Precision:

Sample	Mean (g/dl)	SD (g/dl)	CV %
Pool 1	4.56	0.28	6.20
Pool 2	3.07	0.18	5.90

Method Comparison:
A comparison of the AMS Albumin (y) with a commercial assay (x) gave the following result (n=50):
Y = 1.045x - 0.028; r = 0.992

Interferences:
Icterus: No significant interference up to 110 mg/l of Bilirubin.
Haemolysis: No significant interference up to 1000 mg/l)
Lipaemia: No significant interference up to 1000 mg/dl).

Reference Range:

Adults	3.5 – 5.0 g/dl (35 – 50 g/l)
Newborn (0-4 days)	2.8 – 4.4 g/dl (28 – 44 g/l)
Children 4 days – 14 years	3.8 – 5.4 g/dl (38 – 54 g/l)
Children 14 – 18 years	3.2 – 4.5 g/dl (32 – 45 g/l)

Each laboratory should establish its own mean reference range according to the population.

Note:
The result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Application for Automated systems:
For applications on automated systems – contact technical department.

Quality Control and Calibration Material:
It is recommended that a laboratory uses reference control sera to verify the reagent performance. Results obtained should fall within the specified ranges. If results fall outside these ranges actions should be taken in line with the laboratory's internal quality procedures.
AMS recommend the following calibrator and controls
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

References:

1. Grant GH., *et al* Amino Acids and Protein. In –Fundamentals of Clinical Chemistry, Tietz N.W. Editor, Third Edition, WB Saunders Company Philadelphia USA, 328-329 1987
2. Glick M. R. Ryder K W, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. ClinChem 1986; 32:470-474
3. Doumas BT, Watson WA, Biggs HG. Albumin standards and the measurement of serum albumin with bromocresol green. Clin Chem Acta 1971; 31 87-96
4. Bablok W. et al. A General Regression Procedure of Method Transformation. Clin Chem Clin Biochem 1988

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Keep away from sunlight

CE

Prestige Diagnostics UK Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

V3: rev Dec 2018