MEDTEST DX
A MEDTEST COMPANY

Albumin
Reagent Set

Intended Use
For the quantitative determination of Albumin in serum using the Mindray BS-480 analyzer. *In vitro* diagnostic medical device

Method History
Determination of serum albumin is usually made using an ultra centrifugation, salt fractionation, electrophoretic or dye binding method. Dye binding procedures are the simplest to perform, and lend themselves to high volume testing and automation. They are also the procedures most widely used in combination with total protein determinations to yield an A/G ratio.[1,2] In 1953, the use of methyl orange[3] for direct determination was described. This method suffered from non-specific binding characteristics.[4,5] The use of a HABA[6] dye was introduced in 1954. This method was specific for albumin but displayed poor sensitivity, poor correlation with electrophoresis methods and significant interference from bilirubin, lipids, salicylates, penicillin and sulfonamides.[7]

A bromocresol green (BCG) dye-binding procedure was first proposed in 1964.[8] This procedure exhibited greater sensitivity and much lower susceptibility to interfering substances. The original method has been optimized to improve correlation with electrophoretic methods.[9] The present procedure follows a modification of the original BCG dye-binding procedure.

Several publications of the late 1970's [10,11,12,13] reported that abnormal proteins will bind with BCG after the first minute. The present procedures include a reduced measuring time to eliminate abnormal globulin interference and offers linearity to 8.0 g/dl.

Principle
Albumin is bound by the BCG dye to procedure an increase in the blue-green color measured at 630 nm. The color increase is proportional to the concentration of albumin present.

Reagents
Bromocresol Green (BCG) 0.15 g/L, Buffer, pH 4.66±0.1, surfactant, non-reactive ingredients and stabilizers.

Reagent Preparation
Reagent is in a "ready to use" state.

Reagent Storage and Stability
Store the reagent at room temperature (15-30˚C). The reagent is stable until the expiration date appearing on the label when stored as directed. Manufacturer studies have shown reagent is stable for 30 days once placed in the refrigerated reagent carousel (2-10°C), however reagent stability may vary based on individual laboratory conditions.

Reagent Deterioration
The reagent should be clear, yellow-green solution. Turbidity or precipitation makes the reagent unsatisfactory and it should be discarded.

Precautions and Hazards
1. This reagent is for *in vitro* diagnostic use only.
2. Avoid ingestion.
3. Avoid contact. Reagent is an acid solution. Flush with water when contact occurs.
4. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.

Hazards:
Hazard Classifications: Not a hazardous substance or mixture.
Pictogram: Not required.
Signal Word: Not required.
Hazard Statements: Not a hazardous substance or mixture.
Precautionary Statements: Not a hazardous substance or mixture.
Refer to the Safety Data Sheet for this product (SDS-ALB600) available at www.medtestdx.com.

Specimen Collection and Storage [14]
1. Serum is the specimen of choice.
2. Avoid excessive hemolysis since every 100 mg/dl of hemoglobin corresponds to about 100 mg/dl of albumin.
3. Albumin in serum is reported stable for one week at room temperature (18-30°C) and approximately one month when stored in the refrigerator (2-8°C) and protected against evaporation.

Interferences
1. See Young et al[15] for a list of interfering substances.
2. Ampicillin has been found to seriously interfere with BCG methods.[16]

Materials Provided
Albumin reagent., catalog number: ALB480

Materials Required but not Provided
1. Mindray BS-480 Analyzer.
2. BS-480 Operation manual.
3. Chemistry Calibrator, catalog number CHEC480
4. Chemistry Control, catalog number CHEQ480

Limitations

1. The dye-binding properties of albumin, other than human, differ among species.[17]
2. Samples with values above 8.0 g/dl should be diluted with 0.9% saline 1:1, re-run, and results multiplied by 2. Samples with results below 0.5 g/dl should be done electrophoretically.
3. Severely lipemic serums should have a serum blank.
    A. Add 0.01 ml (10ul) sample to 1.0 ml deionized water and read absorbance against deionized water at 630 nm.
    B. Subtract the serum blank absorbance from the test absorbance and use the corrected absorbance in the calculations.

Calibration

Use MedTest DX Chemistry Calibrator (Catalog Number CHEC480). The procedure should be calibrated according to the instrument manufacturer's calibration instructions. If control results are found to be out of range, the test may need to be re-calibrated. Under typical operating conditions manufacturer calibration stability studies have shown the calibration curve will be stable for at least 14 days.

Quality Control

The validity of the reaction should be monitored by use of normal and abnormal control sera with known albumin concentrations. Quality control requirements should be performed in conformance with local, state, and/or Federal regulations or accreditation requirements. It is recommended that two levels of control material be assayed daily.

Expected Values[1]

3.5 – 5.3 g/dl
It is strongly recommended that each laboratory establish its own normal range.

Performance

1. Assay Range: 0.5 – 8.0 g/dL
2. Comparison: A study was performed between the Mindray BS-480 and a similar analyzer and method, resulted in the following:

Method	Albumin
N	111
Mean Albumin (g/dL)	4.02
Range (g/dL)	0.5-7.8
Standard Deviation	1.54
Regression Analysis	y = 0.971x – 0.14
Correlation Coefficient	0.9899

3. Precision: Precision studies were performed using the Mindray BS-480 analyzer following a modification of the guidelines which are contained in NCCLS document EP5-T2.[18]

Within Day

Sample	LOW	MID	HIGH
N	20	20	20
Mean	2.20	4.58	5.19
Standard Deviation	0.00	0.04	0.04
Coefficient of Variation (%)	0.0%	0.9%	0.7%

Total

Sample	LOW	MID	HIGH
N	40	40	40
Mean	2.23	4.64	5.31
Standard Deviation	0.05	0.09	0.10
Coefficient of Variation (%)	2.2%	2.0%	2.0%

4. Sensitivity: 2 SD Limit of Detection (95% Con Int): 0.0 g/dL

References

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4. Lundh, B., Scand. J. Clin. Lab. Invest. 17:503 (1965).
5. Rosenberg, R.M., et al. J. Am. Chem. Soc. 77:6502 (1955).
6. Rutstein, D.D., et al, J. Clin. Invest 33:211 (1954).
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8. Bartholomew, R., Delany, A., Proc. Australian Assoc. Clin. Biochem. 1:64 (1964).
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CHEMISTRY PARAMETERS

Chem:	ALB	No.:	
Chemistry:	Albumin	Print Name:	ALB
Reaction Type:	End Point	Reaction Direction:	Positive
Pri Wave:	605	Sec Wave:	
Unit:	g/dL	Decimal	0.1
Blank Time:	10 12	Reaction Time:	21 24

	Sample Vol.	Aspirated	Diluent	Reagent Vol.	Diluent
Standard:	2.0 ul	--- ul	--- ul	R1: 200 ul	--- ul
Decreased:	--- ul	--- ul	--- ul	R2: --- ul	-- ul
Increased:	--- ul	--- ul	--- ul	R3: --- ul	-- ul
	☐ Sample Blank	☑ Auto Rerun		R4: --- ul	--- ul

Slope/Offset Adjustment

Slope: 1 Offset: 0

Linearity Range (Standard)	0.5 8	Linearity Limit:	
Linearity Range (Decreased)	____ ____	Substrate Depletion:	
Linearity Range (Increased)	____ ____	Mixed Blank Abs:	
R1 Blank Abs:	____ ____	Uncapping Time	
Blank Response:	____ ____	Reagent Alarm Limit:	
Twin Chemistry:		☐ Enzyme Linear Extension	

☐ Prozone Check ○ Rate Check ○ Antigen Addition

Q1: Q2: Q3: Q4:

PC: ABS:

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CALIBRATION PARAMETERS

Calibrator Definition

Calibrator:	*	Lot No.:	*
Exp Date:	*		

Carousel	Pos
Sample Carousel 1	*
Sample Carousel 2	
Sample Carousel 3	

Reagent/Calibration

Calibrator	Pos	Lot No	Exp Date	Chem	Conc	Unit
Water	W	*	*	ALB	0	g/dL
Chemistry Calibrator	*	*	*	ALB	*	g/dL

Calibration Setup

Chem:	ALB

Calibration Settings

Math Model:	Two-Point Linear		
Factor:		Replicates:	2

Acceptance Limits

Cal Time:	*	Hour	
Slope Diff:	---	SD:	---
Sensitivity :	---	Repeatability:	---
Deter Coeff:	---		

Auto Calib.

☐ Bottle Changed ☐ Lot Changed ☐ Cal Time

It is recommended that two levels of control material be assayed daily.
* Indicates user defined parameter.

REF ALB480

Manufactured for MedTest DX
5449 Research Drive Canton, MI 48188

°30C °15C

IVD

Symbol Key

Use by (YYYY-MM-DD)	LOT Lot and batch code	REF Catalog number	Manufacturer
Temperature limitation	Consult instructions for use	IVD *In vitro* diagnostic medical device	