

Intended Use

For the quantitative determination of Albumin in serum using the Yumizen C560 analyzer. **Rx Only.**

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 orange³ for direct determination was described. This method suffered from non-specific binding characteristics.^{4,5} The use of a HABA⁶ 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-A7502) available by calling 1-734-487-8300.

Specimen Collection and Storage¹⁴

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 al¹⁵ for a list of interfering substances.
2. Ampicillin has been found to seriously interfere with BCG methods.¹⁶

Materials Provided

Albumin reagent., catalog number: 14-A7502-480

Materials Required but not Provided

1. Yumizen C560 Analyzer.
2. Yumizen C560 Operation manual.
3. Pointe Chemistry Calibrator, catalog number C7506-50
4. Pointe Chemistry Control, catalog number C7592-100

Pointe Albumin Reagent Set

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 Pointe Chemistry Calibrator (Catalog Number C7506-50). 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 Values¹

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 Yumizen C560 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 Yumizen C560 analyzer following a modification of the guidelines which are contained in NCCLS document EP5-T2.¹⁸

Sample	Within Day			Total		
	LOW	MID	HIGH	LOW	MID	HIGH
N	20	20	20	40	40	40
Mean	2.20	4.58	5.19	2.23	4.64	5.31
Standard Deviation	0.00	0.04	0.04	0.05	0.09	0.10
Coefficient of Variation (%)	0.0%	0.9%	0.7%	2.2%	2.0%	2.0%

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

References

1. Tietz, N., Fundamentals of Clinical Chemistry, Philadelphia, W.B. Saunders, pp. 335-337 (1976).
2. Davidson, I., Henry, J., Todd-Stanford Clinical Diagnosis by Laboratory Methods, Philadelphia, W.B. Saunders, p 814 (1974).
3. Bracken, J.S., Klotz, I.M., Am. J. Clin. Path. 23:1055 (1953).
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).
7. Arvan, D.A., Ritz, A., Clin. Chim. Acta. 26:505 (1969).
8. Bartholomew, R., Delany, A., Proc. Australian Assoc. Clin. Biochem. 1:64 (1964).
9. Dow, D., Pinto, PVC, Clin. Chem. 15:1006 (1969).
10. Savory, J., et al, Clin. Chem. 22:1102 (1976).
11. Corcoran, R., Duran, S., Clin. Chem. 23:765 (1977).
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13. Gustaffson, J., Clin. Chem. 24:369 (1978).
14. Doumas, B.T., Biggs, H.G., Standard Methods of Clinical Chemistry, Academic Press, N.Y., vol. 7, p. 175 (1972).
15. Young D.S., et al, Clin. Chem. 21:1D (1975).
16. Beng, C.G., Lim, K.L., Am. J., Clin. Path. 59:14 (1973).
17. Spencer, D., et al, Anal. Clin. Biochem. 14:105 (1977).
18. NCCLS document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2nd Ed. (1992).

CHEMISTRY PARAMETERS

Chem:	ALB	No.:	200	Sample Type:	Serum
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 UI	-- ul	-- ul	R1: 200 ul	-- ul
Decreased:	-- UI	-- ul	-- ul	R2: -- ul	-- ul
Increased:	-- UI	-- ul	-- ul	R3: -- ul	-- ul
	<input type="checkbox"/> Sample Blank	<input checked="" type="checkbox"/> 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:			<input type="checkbox"/> Enzyme Linear Extension
<input type="checkbox"/> Prozone Check		<input type="radio"/> Rate Check	<input type="radio"/> Antigen Addition
Q1:	Q2:	Q3:	Q4:
PC:	ABS:		

Pointe Albumin Reagent Set

CALIBRATION PARAMETERS

Calibrator Definition						
Calibrator:	*	Lot No.:	*			
Exp Date:	*					
Carousel		Pos				
Sample Carousel 1	*					
Sample Carousel 2						
Sample Carousel 3						
Reagent/Calibration						
<u>Calibrator</u>	<u>Pos</u>	<u>Lot No</u>	<u>Exp Date</u>	<u>Chem</u>	<u>Conc</u>	<u>Unit</u>
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:	336	Hour				
Slope Diff:	---	SD:	---			
Sensitivity :	---	Repeatability:	---			
Deter Coeff:	---					
Auto Calib.						
<input type="checkbox"/> Bottle Changed	<input type="checkbox"/> Lot Changed	<input type="checkbox"/> Cal Time				

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

REF 14-A7502-480



Manufactured by
HORIBA Instruments Incorporated-Pointe Brand
5449 Research Drive Canton, MI 48188



2°C-8°C



Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

Manufactured by HORIBA Instruments Incorporated – Pointe Brand
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Symbol Key



Use by (YYYY-MM-DD)



Lot and batch code



Catalog number



Manufacturer



Temperature limitation



Consult instructions for use



In vitro diagnostic medical device **Rx Only:** Prescription Use Only