

Intended Use

For the quantitative determination of Albumin in serum using the Yumizen C230 and Yumizen C240 analyzers. **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

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.

Reagent Deterioration

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

Precautions

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.

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.

Materials Required but not Provided

1. Yumizen C230 / Yumizen C240 Analyzer.
2. Yumizen C230 / Yumizen C240 Operation manual.
3. Pointe Chemistry Calibrator, catalog number C7506-50
4. Pointe Chemistry Control, catalog number C7592-100

Test Parameters

Test:	ALB	Chemistry:	Albumin
Chemistry No.:	200	Print Name:	Albumin
Reaction Type:	Endpoint	Reaction Direction:	Positive
Pri. Wave:	630 nm	Sec. Wave:	
Decimal.:	0.1	Samp. Type:	Serum
Blank Time:	0 0	Reaction Time:	3 4
Unit:	g/dL	Incubation Time:	0

	Sample Vol.	Aspirated	Diluent	Reagent Vol.	Diluent
Standard;	2	uL	uL	200	uL
Decreased;		uL	uL		uL
Increased;		uL	uL		uL

Linearity Range (Standard):	0.5-8.0	Linearity Limit:	
Linearity Range (Decreased):		Substrate Depletion:	
Linearity Range (Increased):		Mixed Blank Abs.:	- 40000 40000
R1 Blank Abs.:	- 40000 40000	On-board Stability:	30 Day (s)
Blank Response	- 40000 40000	Reagent Alarm Limit:	5
Twin Chemistry:			

Prozone Check:		
Q1:	Q2:	Q3:
Q4:	PC:	ABS:

Use Qualitative Result:	
Range:	Flag:

Slope Offset:			
Slope	Offset	Unit	
1	0	g/dL	

Pretreatment:	
Pretreat Sample Vol.:	uL
Pretreat Reagent Vol.:	uL

Ref. Range:			
Sample Type:	Gender:	Age Range:	Ref. Range: Critical Range: Unit:

Calibration Setup Parameters

Chem:	ALB			
Calibration Setting	Math Model: Two-Point Linear	Calibrator	Conc.	Pos
	Factor: Replicates: 2	Water	0.0	W
Acceptance Limits		Chem Cal	*	*
Cal Time:	336 hr.			
Slope Diff:	SD:			
Sensitivity:	Repeatability:			* User Defined
Deter Coeff:				
Auto Calib.				
	<input type="checkbox"/> Cal Time			

Pointe Albumin Reagent Set

Limitations

- The dye-binding properties of albumin, other than human, differ among species.¹⁷
- 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.
- Severely lipemic serums should have a serum blank.
 - Add 0.01 ml (10ul) sample to 1.0 ml deionized water and read absorbance against deionized water at 630 nm.
 - Subtract the serum blank absorbance from the test absorbance and use the corrected absorbance in the calculations.

Calibration

Use an NIST-traceable serum calibrator. The procedure should be calibrated according to the instrument manufacturer's calibration instructions. If control results are found to be out of range, the procedure should be re-calibrated.

Calculation (Example)

Abs. = Absorbance

$$\frac{\text{Abs. of Unknown}}{\text{Abs. of Standard}} \times \text{Conc. of Std.} = \text{Albumin (g/dl)}$$

Example: If the Absorbance of the Unknown = 0.200 and the Absorbance of the Standard is 0.19 and the Standard Concentration = 3.5, then:

$$\frac{0.200}{0.190} \times 3.5 = 3.68 \text{ g/dl}$$

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.

Expected Values¹

3.5 – 5.3 g/dl

It is strongly recommended that each laboratory establish its own normal range.

Performance

- Linearity: 0.5 – 8.0 g/dl
- Comparison: A study was performed between the Yumizen 200 series analyzers and a similar analyzer and method, resulted in a correlation coefficient of 0.952 with a regression equation of $y = 1.076x - 0.30$ (n=29).
- Precision: Precision studies were performed using the Yumizen 200 series analyzers following a modification of the guidelines which are contained in NCCLS document EP5-T2.¹⁸

Within Run			Day to Day		
Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
2.92	0.10	3.3	3.15	0.06	1.9
4.44	0.08	1.8	4.84	0.11	2.3

References

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Symbol Key

Use by (YYYY-MM-DD)	Lot and batch code
Catalog number	Manufacturer
In vitro diagnostic medical device	Temperature limitation
Consult instructions for use	Rx Only: Prescription Use Only
CE mark	Authorized representative in the European Community

12-A7502-160	Manufactured by HORIBA Instruments Incorporated - Pointe Brand 5449 Research Drive Canton, MI 48188		
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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.