



ALBUMIN (BCG) REAGENT
C244-01

Contents	Product No.	Package
ALBUMIN REAGENT	C244-01	1 x 500 mL

REAGENT PREPARATION

This reagent is packaged ready for use.
No preparation is required.

REAGENT STORAGE AND STABILITY

Store unopened reagents at 15-30°C or at 2-8°C.
When stored as directed, the reagent is stable until the expiration date stated on the label.

NOT FOR USE IN UNPROFESSIONAL SETTINGS

FOR TECHNICAL ASSISTANCE:
Email: catachem@catacheminc.com
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ALBUMIN (BCG) REAGENT
C244-01
MANUAL/AUTOMATED APPLICATION

Intended Use

For IN VITRO quantitative determination of Albumin in serum or plasma using manual or automated applications.

Clinical Significance

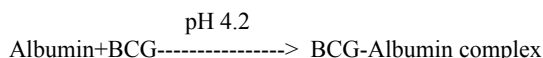
Measurements of Albumin are used primarily for diagnosing liver and kidney diseases, as well as for monitoring the causes and treatments.

Method History

Rodkey in 1965 reported the use of 3,3,5,5 tetrabromo-m-cresolphthalein (BCG) as a specific Albumin binding dye for the quantitation of Albumin in serum. Doumas, et al optimized the BCG-reaction pH for better specificity and adjusted the concentration of polyoxyethylene-23-lauryl ether (Brij-35) to maximize linearity, prevent turbidity and to reduce the absorbance of the reagent baseline at 630nm.

Method Principle

BCG dye at a pH of 4.2 and in the presence of non-ionic surfactants including Brij-35, specifically binds Albumin to form a colored BCG-Albumin complex with maximum absorbance at 630nm. The increase in absorbance is directly proportional to the Albumin concentration present in the sample.



Reagent Content

The concentrations of the active ingredients in the reagents are approximately as follows.

BCG Reagent

- Each liter contains:
Water
BCG 0.32 mmol/L
Buffer
Nonreactive ingredients and stabilizers

Precautions

Avoid contact of reagent with skin and eyes. Should contact occur, wash affected area with plenty of cold water. DO NOT PIPETTE REAGENTS BY MOUTH.

Preparation of Working Reagents

Catachem's BCG Reagent is in ready-to-use form.

Reagent Storage and Stability

Store unopened reagents at 15-30°C or at 2-8°C. When stored as directed, this reagent is stable until the expiration date stated on the label. The Catachem Albumin Reagents have been tested to reflect shipping conditions and are stable for the lifespan of the product if frozen up to 5 times or upon reaching temperatures up to 40°C for up to one week.

Specimen Collection and Preparation

Test sera should be fresh, clear and non-hemolyzed. When blood is drawn, it should be processed as soon as possible and the serum should be isolated from the clot without delay.

Interfering Substances

Slight or moderate lipemic serum, containing more than 800 mg/dL Triglycerides could increase the Albumin values by 0.2 g/dL or greater. Samples with Bilirubin content of up to 30 mg/dL do not significantly affect the Albumin values. Samples with Hemoglobin content of 300 mg/dL or less do not affect the Albumin results. A summary of the influence of drugs on clinical laboratory procedures may be found by consulting D.S. Young, et al.

Expected Values

Normal serum from a healthy human adult contains about 3.5 to 5.0 g of Albumin/dL, averaging about 4.5. These values are suggested guidelines. It is recommended that each laboratory establish the normal range for the species under evaluation and for the area in which the laboratory is located.

Procedure

Important: Read the entire procedural instructions before proceeding with assay.

Materials Required (Not Provided)

- Spectrophotometer
Match cuvettes 1 cm light path
Timer to time incubation
Pipette Appropriate to dispense 1 ml
Pipette Appropriate to dispense 8 µl
Constant temperature incubator for assays at 37°C

Materials Provided

Albumin BCG Reagent.

Analytical Parameters

- Wavelength 630nm
Temperature 37°C
Pathlength 1 cm
Reaction Mode Endpoint
Reaction Time 60 seconds
Reaction Volume 1.0 ml
Sample Volume 0.008 ml
Total Volume 1.008 ml
Sample-to-reagent ratio 1:126

Assay Procedure

- 1. Pipette 1.0 ml of BCG reagent into each of three cuvettes marked "Calibrator", "Sample", and "Blank".
2. Pipette 0.008 ml of sample(s) and calibrator into their respective cuvettes. Use 0.008 ml water for the blank. Mix all cuvettes well.
3. Incubate all cuvettes for 1.0 minute at 37°C.
4. Set spectrophotometer wavelength at 630nm and zero the instrument with the cuvette marked "blank".
5. Read the "Calibrator" and "Sample" absorbencies.
6. Calculate the Albumin concentration (g/dL) in the sample(s), as shown in results and calculations.



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Results and Calculations

$$\text{ALB (g/dL)} = \frac{\text{Sample Absorbance}}{\text{Calibrator Absorbance}} \times \text{calibrator (g/dL)}$$

Example:
 sample absorbance = 0.300
 calibrator = 0.250
 calibrator value = 4.0 (g/dL)

$$\text{ALB (g/dL)} = \frac{0.300}{0.250} \times 4.0 = 4.8 \text{ g/dL}$$

Quality Control

To monitor the performance of the reagent and the procedure used, we recommend the regular use of a normal and abnormal control serum.

Method Performance Characteristics

Sensitivity: The sensitivity of this method is 0.140-0.180 absorbance units per g/dL.

Linear Range: In this method there is no significant nonlinearity over the range of 0-6 g/dL.

Precision: Within-run and day-to-day precision are summarized below.

Precision Study

ALBUMIN	Within-Run Precision		Total Precision	
	Mean	SD	SD	CV
g/dL	g/dL	%	g/dL	%
1.2	0.04	3.5	0.05	4.3
3.4	0.05	1.4	0.07	2.0
5.6	0.06	1.1	0.06	1.0

Correlation

A comparison of this method using an automated analyzer and a reference method based upon the BCG reaction resulted in the following regression statistics.

Range = 1.6 - 5.2 g/dL
 N = 197
 Y = 1.039 - 0.12
 r = 0.999
 Sy.x = 0.09

References

1. Fundamentals of Clinical Chemistry edited by Norbert Tietz. WB Saunders, Philadelphia (1976).
2. Rodkey FL. Direct spectrophotometric determination of albumin in human serum. Clin Chem 11 (1965).
3. Dumas BT, Watson WA, Biggs HG. Albumin standards and the measurements of serum albumin with bromocresol green. Clin Chem Acta 31, 87-96 (1971).
4. Young DS, Pestaner LC, Gibberman V. Effects of drugs on clinical laboratory tests. Clin Chem 21, No 5 (1975).