Albumin Reagent

Catalog #: 43701

for use with the

SDI CA480 Clinical Chemistry System

INTENDED USE
This reagent is intended for the in vitro quantitative determination of albumin in human serum.

CLINICAL SIGNIFICANCE[1]
Observations of serum albumin level is useful as an aid in diagnosing disease states of the liver and kidneys. Moderate to large changes in the concentration of albumin have significant effects on the relative amounts of the bound and free concentrations of the ligands it carries: because free ligands are those that interact with tissue receptor sites and that can be excreted, albumin levels have important influences on the metabolism of endogenous substances such as calcium, bilirubin, and fatty acids and on the effects of drugs and hormones.
Hypoalbuminemia is very common in many illnesses and results in most instances from one or more of the following factors: 1) impaired synthesis, 2) increased catabolism, 3) reduced absorption of amino acids, 4) altered distribution which may sequester large amounts of albumin in an extravascular compartment, 5) protein loss by way of urine or feces.

METHODOLOGY [2,3]
At a controlled pH, bromcresol green forms a colored complex with albumin. The intensity of color at 630 nm is directly proportional to albumin content. The instantaneous initial absorbance is obtained as suggested by Webster

The method used by SDI Albumin Reagent is based on that of Doumas

Principle:

BCG + Albumin —(Controlled pH)→ **Green BCG/Albumin Complex**

REAGENT COMPOSITION

Active Ingredients	Concentration
Bromcresol Green	0.25 mmol/L
Succinate Buffer	85 mmol/L
Surfactant	
PH 4.20	

Precautions and Warnings:
1. For *in vitro* diagnostic use only.
2. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the SDI Albumin Reagent Material Safety Data Sheet.
3. 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.
4. Do not use the reagent after the expiration date printed on the kit.

REAGENT PREPARATION
Reagent is supplied ready to use.

STABILITY AND STORAGE
When stored at 2-25°C, the reagent is stable until the expiration date stated on the label.

REAGENT DETERIORATION
The reagent should not be used if:
1. The reagent is turbid.
2. The reagent fails to meet stated parameters of performance.

SPECIMEN COLLECTION AND HANDLING[3]
Collection: No special preparation of the patient is necessary and sample preservatives are not required.
Sample Type: Serum is the recommended specimen. Collect blood into the appropriate sample tube by venipuncture.

Storage: Albumin in serum is stable for one month at 2-8°C.

INTERFERENCES
Studies to determine the level of interference for hemoglobin, bilirubin, and lipemia were carried out, the following results were obtained:

Hemoglobin:
No significant interference from hemoglobin up to 1000 mg/dL.

Bilirubin:
No significant interference from bilirubin up to 14.8 mg/dL.

Lipemia:
No significant interference from lipemia up to 930 mg/dL measured as triglycerides.

A number of drugs and substances may affect the accuracy of Albumin. See Young, et al.[4]

ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED
1. SDI CA480 Clinical Chemistry System
2. Deionized water and related equipment, e.g.: pipettes
3. Analyzer specific consumables, e.g.: sample cups
4. Control, and Calibrator materials such as those provided by SDI Biomed.

ASSAY PROCEDURE

Albumin	System Parameters
TEMPERATURE:	37°C
WAVELENGTH:	630 nm
ASSAY TYPE:	Endpoint
DIRECTION:	Increase
SAMPLE / RGT RATIO:	1 : 100
e.g. Sample Vol.	0.01 mL (10mL)
Reagent Vol.	1.0 mL
INCUBATION:	less than 90 seconds

Procedure Notes:
1. The temperature of the reaction is not critical, however the temperature should be held constant.
2. Unit Conversion: g/dL x 10 = g/L

Calculations:
(A = Absorbance)

$$\frac{A\ patient}{A\ standard} \times \text{Concentration of standard (g/dL)} = \text{Albumin (g/dL)}$$

Example:
A patient = 0.200
A (standard)= 0.190
Concentration of standard = 3.5 gldL.

$\frac{0.200}{0.190} \times 3.5 = 3.68$ g/dL Albumin

Limitations
Samples with values exceeding 6.0 g/dL should be diluted 1:1 with saline and re-run. The final answer should be multiplied by two.

CALIBRATION
Use an aqueous Albumin standard or an appropriate serum calibrator.

QUALITY CONTROL
The integrity of the reagent should be monitored by use of a two level control with known Albumin values.

EXPECTED VALUE[1]
3.5 – 5.0 g/dL

It is highly recommended that each laboratory establish its own reference range.

PERFORMANCE
Linearity:
When run as recommended the assay is linear to 6.0 g/dL

Method Comparison:
Studies performed between this procedure and a similar methodology yielded the following results:

Number of samples pairs:	43
Range of samples:	0.80– 5.80 (g/dL)
Correlation Coefficient:	0.987
Slope:	0.988
Intercept:	0.12 (g/dL)

Precision:

Within Run	Level 1	Level 2
n=40		
Mean (g/dL)	3.23	2.17
S.D. (g/dL)	0.04	0.04
C.V. (%)	1.2	1.9

Total
n=40 (10 days / 2 runs per day / 2 replicates per run)

Mean (g/dL)	3.23	2.17
S.D. (g/dL)	0.06	0.06
C.V. (%)	1.8	2.6

Sensitivity:
A calibration factor of approximately 7.35 was obtained, which is equivalent to a sensitivity of 0.136 D Abs per g/dL.

REFERENCES

1. Tietz, N., Textbook of Clinical Chemistry, Philadelphia, W.B. Saunders, 1986 pp. 701-704
2. Webster D: 177. The Immediate Reaction between Bromcresol Green and Serum as a Measure of Albumin Content. Clin Chem 23:663
3. Doumas BT, Warson WA, and Biggs NG: 1971. Albumin Standards and the measurement of Serum Albumin with Bromcresol Green Clin Chem Acta 31:87
4. Young DS, Effects of Drugs on Clinical Laboratory Tests. Third Edition 1990;12-6

Manufactured for:

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