

Albumin Reagent

INTENDED USE

For the quantitative determination of Albumin in serum.

SUMMARY

Serum albumin levels have been determined by a variety of methods including salt fractionation, electrophoresis, immunochemical techniques and measurement of albumin directly, by virtue of the tendency of albumin to bind certain dyes such as bromocresol green, methyl orange, and HABA dye.

The Thermo Albumin Procedure is a dye-binding method based on the original work of Rodkey¹ as modified by Doumas, et. al.² The addition of albumin to solutions of certain dyes results in the formation of a dye-binding complex that exhibits optical properties different from that of the free dye. The bromocresol green reaction is recognized as being more specific and reproducible than other dyes for the determination of serum albumin.^{1,3}

METHODOLOGY

albumin + bromocresol green → green chromogen

The Thermo Albumin Procedure is based on the dye-binding capabilities of serum albumin. Albumin reacts with bromocresol green at an acid pH to form a green color. The increase in color is measured spectrophotometrically and is proportional to the amount of albumin present.

REAGENTS

Reactive Ingredients

Albumin Buffer (R1)

buffer
surfactant
sodium azide

Albumin Color (R2)

bromocresol green	1.24 mmol/L
succinic acid	440 mmol/L
surfactant	
sodium azide	
buffer	

Precautions

For in vitro diagnostic use.

Color (R2): Contains acid. Do not pipette by mouth; do not ingest. Avoid contact with skin, eyes, and clothing. External contact: wash with soap and water. Seek medical attention if irritation develops.

Buffer (R1), Color (R2): Contains sodium azide. Sodium azide may react with lead joints in copper drain lines to form explosive compounds. Drains should be well flushed with water when discarding the reagent. Avoid contact with eyes, skin and clothing. Do not ingest.

Preparation

The reagents are ready to use as supplied.

Storage and Stability

1. The unopened reagents are stable until the expiration date stated on the label when stored at 2° - 30°C.
2. After opening, the reagents are stable for 21 days when stored at 2° - 30°C and kept covered.

Deterioration

1. Albumin Buffer (R1) should be a clear colorless solution.
2. Albumin Color (R2) should be a clear yellow-green solution.
3. Presence of turbidity or a precipitate could indicate deterioration and the reagent should not be used.
4. Failure to achieve assay values on freshly prepared control sera could indicate deterioration.

SPECIMEN COLLECTION

Clear, non-hemolyzed serum is the recommended sample.⁴

SAMPLE STORAGE

Albumin in serum is stable for up to one week at room temperature, approximately one month refrigerated, and longer when frozen.⁵

INTERFERING SUBSTANCES

1. Hemolysis, moderate lipemia and slightly elevated bilirubin do not cause significant interference with this assay.
2. This procedure is based upon the dye-binding properties of albumin and because many drugs are bound to albumin in the body, medication interference must be considered for each individual patient. Ampicillin and other medications have been found to seriously interfere with this reaction.³
3. Young has reviewed drug effects on serum albumin levels.⁶

PROCEDURE

Test Parameters

Refer to the Thermo Reagent Applications.

MATERIALS PROVIDED

- | | | | |
|----|----------|---------------------|------------|
| 1. | 7500-102 | Albumin Buffer (R1) | 4 x 500 mL |
| 2. | 7500-202 | Albumin Color (R2) | 4 x 175 mL |

MATERIALS REQUIRED BUT NOT PROVIDED

1. Analyzer with Manual and Accessories.
2. Thermo Reagent Applications.
3. Thermo Data-Cal (Cat. No. 1905-505 or TR43001) or equivalent.
4. Thermo Data-Trol N and Data-Trol A (Cat. No. 1902-050 or TR40001 and 1901-050 or TR41001) or equivalent.

STABILITY OF FINAL REACTION MIXTURE

The instrument automatically computes every determination at the same time interval.

CALIBRATION

Thermo Data-Cal (Cat. No. 1905-505 or TR43001) or equivalent should be used to calibrate the assay.

LINEARITY

Linearity extends to 6.0 g/dL. Samples exceeding linearity should be diluted with normal saline and repeated. Multiply the result by the dilution factor when calculating the unknown.

QUALITY CONTROL

Normal and abnormal control sera of known concentrations of albumin should be analyzed routinely with each group of unknown samples. Thermo's Data-Trol N and Data-Trol A (Cat. No. 1902-050 or TR40001 and 1901-050 or TR41001) are recommended for this purpose.

CALCULATION OF RESULTS

Results, expressed in g/dL at 37°C, are automatically calculated.

LIMITATIONS

See Storage and Stability, Deterioration, Specimen Collection, Interfering Substances, Sample Storage, and Linearity sections for limitations to this procedure.

EXPECTED VALUES

An observed range for albumin, derived from a study of 52 asymptomatic adults in the Southwest USA, was found to be 4.1 - 5.3 g/dL. A reference range of 3.5 - 5.5 g/dL has been reported in the literature.⁴ These ranges should serve only as guidelines. It is recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories, and local populations.

PERFORMANCE CHARACTERISTICS**Precision**

Within-run precision was determined by assaying control in replicate.

Within-run	n	mean	std.dev	CV%
LEVEL 1	18	2.0	0.01	0.49
LEVEL 2	18	3.6	0.03	0.83

Run-to-run precision was determined by assaying control sera in duplicate for 10 runs.

Run-to-run	n	mean	std.dev	CV%
LEVEL 1	20	2.1	0.06	2.86
LEVEL 2	20	3.7	0.10	2.70

SENSITIVITY

Based on an instrument resolution of A = 0.001, this Thermo Albumin Procedure has a sensitivity of 0.2 g/L.

BIBLIOGRAPHY

1. Rodkey, F.L., Clin. Chem. 2, 1965, p. 478.
2. Doumas, B.T., Watson, W.A., Biggs, H.G., Clin. Chim. Acta 31, 1971, p. 87-96.
3. Beng, C.G., and Lim, K.L., Am. J. Clin. Path. 59, 1973, p. 14.
4. Tietz, N.W., Textbook of Clinical Chemistry, W.B. Saunders, Philadelphia, 1986, p. 588.
5. Doumas, B.T., and Biggs, H.G., Standard Methods of Clinical Chemistry, Academic Press, New York, 1976, p. 175.
6. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 3rd ed., AACC Press, Washington, DC, 1990, p. 3-12 - 3-16.

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REF

Reorder Information

Catalogue No.	Configuration
7500-102	4 x 500 mL Reagent 1
7500-202	4 x 175 mL Reagent 2