TRUEchemie Albumin Test Kit (Bromocresol Green)

for the quantitative determination of Albumin concentration in human serum or plasma

INTENDED USE

The TRUEchemie Albumin Test Kit (Bromocresol Green) is used for the quantitative determination of Albumin concentration in human serum or plasma.

INTRODUCTION

Albumin is the most abundant protein constituent of serum. It is synthesized in the liver and is noted for its ability of configuration changes. This steric affinity allows the albumin molecule to serve as carrier of many substances such as bilirubin, fatty acids, uric acid, various drugs and antibiotics. Albumin also functions in the maintenance of proper osmotic pressure.

Elevated serum albumin levels are associated with possible dehydration. Low serum, albumin levels are indicative of potential malnutrition, liver disease, kidney disorders and rheumatoid arthritis.

Earlier, salt fractionation methods used to determine serum albumin were too laborious to perform and hence it is replaced by azo dye methods. The use of bromcresol green in the reaction has become the preferred method because of its negligible interference for hemolysis, bilirubin and salicylates.

PRINCIPLE

At a certain pH value, albumin is specifically combined with bromcresol green, to produce a coloured complex, which is photometrically measured.

PACK SIZE

Kit size	**2 x 50 ml**
Cat. no.	**ADX271**
Kit contents	
1) Albumin Reagent	2 x 50 ml
2) Albumin Standard (4 g/dL)	1 x 5 ml

REAGENT COMPOSITION

1) Albumin Reagent:
Phosphate buffer pH 4.0 : 70.00 mmol/L
BCG : 0.25 mmol/L
Preservatives and stabilizers
2) Albumin Standard : 4 g/dL

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. The reagent contains sodium hydroxide that is corrosive. In case of contact with skin, flush with water and for eyes, seek medical attention.
5. The disposal of the residues has to be done as per local legal regulations.

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. The absorbance is used to calculate the results.

REAGENT STORAGE & STABILITY

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2-8°C. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND STORAGE

Serum (or) plasma.
Sample may be stored for 4 weeks at 2 - 8°C, or 4 months at -20°C.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Test tubes/rack
3. Timer
4. 37°C heating block or water bath
5. Photometer capable of accurately measuring absorbance at 630 nm

TEST PROCEDURE

Primary wavelength 630 nm
Temperature 37°C
Prewarm the reagent to reaction temperature.

	Blank (µl)	Standard (µl)	Sample (µl)
Albumin Reagent	1000	1000	1000
Albumin Standard	--	10	--
Sample	--	--	10

Mix well and incubate for 3 min at 37ºC or 5 min at room temperature (20 - 25°C). After incubation, zero the Photometer with the reagent blank. Read and record the incubated standard and samples.

Calculation: $\frac{\text{Sample OD}}{\text{Standard OD}}$ x 4 = g Albumin / dL

S.I. Units (g/dl) x 10 = mmol/L

QUALITY CONTROL

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED VALUE

Serum, plasma: 3.5 - 5.3 g/dL
It is strongly recommended that each laboratory establish its own normal range

PERFORMANCE CHARACTERISTICS

Sensitivity: 0.13 g/dL
Linearity: Up to 7.5 g/dL under the described assay conditions. Samples that have Albumin values greater than 7.5 g/dL should be diluted with saline water (NaCl 0.9 %) 1:1, re-assayed and the results multiplied by 2. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	**Mean (g/dL)**	**SD (g/dL)**	**CV (%)**
Control Level - 1	4.2	0.1	2.1
Control Level - 2	2.6	0.1	0.8

Inter-assay precision run to run (n=12)	**Mean (g/dL)**	**SD (g/dL)**	**CV (%)**
Control Level - 1	4.2	0.1	2.9
Control Level - 2	2.5	0.1	3.3

The reagent was tested for 12 days, using two different Albumin concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Albumin reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.952 and the regression equation is y=0.973x+0.105. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

1. Ampicillin and other medications seriously interfere with the dye binding properties of albumin.
2. It is also recommended that only standards and controls containing human albumin be employed with this procedure.
3. The dye-binding properties of albumin from various species have been found to differ widely.

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	End point
Std. conc.	:	4
Wave length	:	630 nm
Units	:	g/dL
Flow cell temp.	:	37°C
Blank	:	Reagent
Reagent volume	:	1000 µL
Sample volume	:	10 µL
Incubation	:	3 min. at 37°C
Low normal	:	3.5
High normal	:	5.3
Sensitivity	:	0.13
Linearity	:	7.5
Reaction Slope	:	Increasing

REFERENCES

1. Holvey, D.N., ed.: The Merck Manual of Diagnosis and Therapy, erck and Co., Inc. Rahyway, N.J. (1972).
2. Cooper, G.R., CRC Crit Rev. Clin Lab. Sci. 4:101 (1973).
3. Keston, A.S., Colorimetric, "Enzymatic Reagents for Glucose". Abstracts of Papers, 129th Meeting ACS, 131C (1956).
4. Trinder, P., "Determination of blood glucose using 4aminophenazone." J. Clin. Path. 22:246 (1969).
5. Tietz, N.W., Fundamentals of Clin. Chem., Philadelphia, W.B. Saunders (1970). Young, D.S. et al., Clin. Chem. 21:5 (1975).
6. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
2°C 8°C Temperature limit 2-8 °C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
Do not use if package is damaged	Keep away from sunlight	

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