

Ana-Chek® ALBUMIN

METHOD – BROMOCRESOL GREEN

PRODUCT CODE – LA03

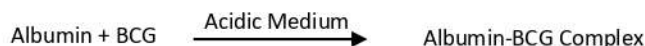


INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Albumin in serum / plasma using Bromocresol Green method.

SUMMARY AND PRINCIPLE

Albumin level is decreased in severe liver diseases, malabsorption, diarrhoea, eclampsia and nephrosis. The level is increased in dehydration. Ana-Chek® Albumin is a single reagent kit for quantitative determination of albumin in human serum and plasma based on BCG method.



KIT COMPONENTS

Reagent 1 : Bromocresol Green Reagent
Reagent 2 : Albumin Standard (5gm/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Ana-Chek® Albumin is a ready to use single reagent. The reagent kit should be stored at 2-8 °C and is stable till the expiry date indicated on the label. Protect the reagent from direct light.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.100 O.D. against D/W at 600 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Albumin	Reagent Volume	1000 µl
Reaction Type	End Point	Sample Volume	10 µl
Wavelength	600 nm	Incubation Temperature	R.T.
Flow Cell Temp.	37 °C	Incubation Time	1 min
Blank setting	Reagent	Standard Conc.	5 gm/dL
Blank abs. limit	< 0.100	Linearity	6 gm/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum, heparinized or EDTA plasma can be used. Avoid venous stasis. Albumin in serum / plasma is stable for 2 days at 2-8 °C and 6 months at -20 °C.

COMPONENTS OF REAGENT

Component	Concentration
Succinate Buffer, pH 3.6	100 mmol/l
Bromocresol Green	0.15 mmol/l
Stabilizers and inactive ingredients.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	10 µl	NA
Sample	NA	NA	10 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 1 minute at room temperature.			
Aspirate reaction mixture into flow cell and measure the absorbance.			
The final colour is stable for 10 mins if not directly exposed to light.			

CALCULATION

$$\text{Albumin (gm/dL)} = \frac{\text{Abs. of sample} \times 5}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

3.5 – 5.0 g/dL

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 0.1 - 6 g/dL. If the Albumin value exceeds linearity limit (above 6 g/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Albumin value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (g/dL)	SD (g/dL)	CV %	Mean (g/dL)	SD (g/dL)	CV %
Low Value Serum	2.68	0.04	1.7	2.33	0.05	2.1
High Value Serum	4.15	0.04	1.4	3.82	0.08	2.1

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Albumin. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the reagent if its absorbance exceeds 0.100 at 600 nm against distilled water.
2. If Albumin value exceeds 6 gm/dL then dilute the specimen suitably with normal saline & repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain the correct Albumin value.
3. The test is not influenced by bilirubin values upto 25 mg/dL and 600 mg/dL haemoglobin but gross haemolysis should be avoided.
4. A marked lipemia will interfere. A sample blank must be determined by pipetting 10 µl sample to 1 ml normal saline and measured against distilled water. The absorbance of sample blank has to be subtracted from the absorbance of the sample.

BIBLIOGRAPHY

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Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry