SyRe Accute

AGAPPE

ALBUMIN

4 x 50 mL
12006001

Intended Use
This reagent is intended for *in vitro* quantitative determination of Albumin in serum or plasma.

-Bromocresol green methodology

-Linear up to 6 g/dL

Clinical Significance
Albumin which is synthesized in the liver constitute a major part of the total proteins in the body, the other part being globulin; form the major portion of the dissolved substances in the plasma. Functions of Albumin includes distribution of extracellular fluid, regulation of osmotic pressure, acts as transport agent for a wide variety of substance such as hormones, lipids, vitamins etc.

Increased levels are seen in dehydration.

Decreased levels are seen in liver disease (Hepatitis, Cirrhosis), malnutrition, kidney disorders and increased fluid loss during extensive burn & malabsorption.

Principle
The reaction between albumin from serum or plasma and the dye bromocresol-green produces a change in colour that is proportional to the albumin concentration.

Kit Components

Reagent/ Component	Product Code 12006001	Description	
Albumin Reagent	4 x 50 mL	Succinate Buffer (pH 4.20) Bromocresol green	75 mmol/L 0.14 g/L

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation
Albumin reagent is ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at room temperature.

Open Vial Stability
Once opened the reagents are stable up to 60 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 10 days.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum / plasma (Do not use lipemic or hemolysed sample)

Interferences
No interference for

Ascorbic acid up to	50 mg/dL
Bilirubin up to	20 mg/dL
Haemoglobin up to	1000 mg/dL

Materials provided
Albumin reagent

Reagents required but not provided
Multicalibrator (Product Code: 11610001), Qualicheck Norm (Product Code: 11601003), Qualicheck Path (Product Code: 11601002)

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
g/dL	g/L	x 10

Calibration
Agappe Multicalibrator (Product Code: 11610001) is recommended for calibration of the assay.

Quality control
It is recommended to use Qualicheck Norm (Product Code: 11601003) or Qualicheck Path (Product Code: 11601002) to verify the performance of the measurement procedure.

Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.

Serum / Plasma : 0-4 days	:2.8 - 4.4 g/dL
4 days-14 years	:3.8 - 5.4 g/dL
14-18 Years	:3.2 - 4.5 g/dL
Adult (20-60 years)	:3.5 - 5.2 g/dL
60-90 Years	:3.2 - 4.6 g/dL
>90 Years	:2.9 - 4.5 g/dL

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 6 g/dL. If the concentration is greater than linearity (6 g/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.968 and a regression equation of y = 1.0124x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (g/dL)	4.3	3.1	4.2	3.0
SD	0.15	0.11	0.14	0.10
CV(%)	3.4	3.5	3.3	3.3

Accuracy (g/dL)		
Control	Expected Value	Measured Value
Control Level 1	4.3 ± 0.6	4.2
Control Level 2	2.97 ± 0.42	3.0
Qualicheck Norm	4.5 ± 0.70	4.5
Qualicheck Path	3.4 ± 0.6	3.35

4. Sensitivity
Lower detection Limit is 0.1 g/dL

Bibliography

1. Doumasa B.T.*et al*: Clin. Chim Acta 31, 87 pp (1971)
2. Weis, W.A. :Klin. Wochenschr. 43, S.273 (1965)
3. Burtis, Ashwood, Bruns & Saunders : Tietz Text Book of Clinical Chemistry 4th Edition -2006.

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

AGAPPE DIAGNOSTICS LTD.
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REV. NO.: ADL/IFU/ALB/40FR/R01

CE ISO 9001:2015
EN ISO 13485:2016

ALBUMIN

4 x 50 mL
12006001

Accute 40 FR Assay Parameter

Page 1	
Test	ALBUMIN
Reaction Mode	End
Reference Test ID	**
Test WL	604
Blank WL	
Test Read Timing	42-44
Blank Read Timing	
Sample	2 µL
R1	200 µL
R2	
Stirrer	OFF
Cal Mode	std
Page 3	
Calibration Mode	Linear
** Not applicable	
# - Input Programme Number only for sample Blanking parameters	

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