Albumin Assay Kit (ALB)

Method: Bromocresol Green

Cat .No.	Size	Instrument
GB0920G	R1: 6×100 ml	For Hitachi 7060/7150 & Shimadzu CL7200/8000
GS0921G	R1: 8×70 ml	For Hitachi 7170 & OlympusAU640/400/600
GH0921G	R1: 6×50 ml	For Hitachi 7020
GT0921G	R1: 7×50 ml	For TOSHIBA 40
GX0921G	R1: 2×100 ml	For SYNCHRON CX4-5-7-9/LX20

INTENDED USE
For the *in vitro* quantitative determination of Albumin in serum.

CLINICAL SIGNIFICANCE[1,2]
Albumin consists of approximately 60% of the total proteins in the body, the other major part being globulin. It is synthesized in the liver and maintains the osmotic pressure in blood. Albumin also helps in the transportation of drugs, hormones and enzymes. Elevated levels are rarely seen and are usually associated with dehydration. Decreased levels are seen in liver diseases (Hepatitis, Cirrhosis). Malnutrition, kidney disorders, increased fluid loss during extensive burns and decreased absorption in gastro-intestinal diseases.

ASSAY PRINCIPLE
Albumin binds with the dye Bromocresol Green in a buffered medium to form a green coloured complex. The intensity of the colour formed is directly proportional to the amount of albumin present in the sample at 600 nm.

SAMPLE COLLECTION AND PREPARATION
Serum samples.
Use fresh patient serum. Serum samples are stable for 2 weeks at 2-8°C, or for 6 months at -20°C.

REAGENT COMPOSITION

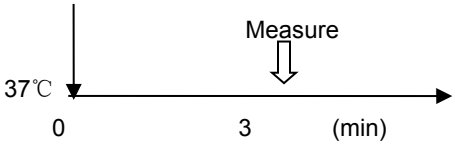
Contents	Concentration of Solutions
Reagent 1	
Succinate buffer	75 mmol/L
Bromocresol green	0.15 mmol/L
Brij-35	

STABILITY AND PREPARATION OF REAGENTS
Reagent is ready to use. Protect from bright light. Stable up to the expiry date when stored at 2-8℃.

ASSAY PROCEDURE
Test Procedure for Analyzers (HITACHI 917)

Assay Mode: End Point
Wave Length (main/sub): 600 nm/700 nm

Sample:2 µl
R1: 200 µl



1. Mix 2 µl sample with 200 µl R1 and incubate at 37℃ for 3 minutes.
2. Measure the absorbance of the sample (A_{sample}) and calibrator ($A_{calibrator}$) against reagent blank.

CALCULATION

$$\text{Concentration} = \frac{A_{sample} - A_{blank}}{A_{calibrator} - A_{blank}} \times \text{Calibrator value}$$

CALIBRATION
Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL
Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

REFERENCE VALUE[2]
Adult Serum: 38 - 44 g/L (3.8 - 4.4 g/dl)
Neonatal Serum: 38 - 42 g/L (3.8 - 4.2 g/dl)
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS
LINEARITY
When run as recommended the assay is linear up to 66.0 g/L. If the samples above this concentration should be diluted with 0.9% NaCl and repeat assay. Multiply the result by dilution factor.

PRECISION
The CV of the test should be CV ≤5%.

Inter assay precision		
N=5	Level1	Level 2
Mean (g/L)	42.85	29.30
SD	0.42	0.34
CV	0.99%	1.18%
Intra assay precision		
N=20	Level1	Level 2
Mean (g/L)	40.02	29.45
SD	0.35	0.32
CV	0.88%	1.09%

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INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin:	500 mg/dl
Intralipid:	1000 mg/dl
Bilirubin:	50 mg/dl
Ascorbic Acid:	50 mg/dl
Heparin Na	100 U/ml

SAFETY PRECAUTIONS AND WARNINGS

1. For *in* vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent

   azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Grant G.H., et al Amino Acids and Proteins ;Fundamentals of Clinical Chemistry, Tietz N.W. Editor,Third Edition, WB Saunders Company PhiladelphiaUSA, 328-329, 1987
2. Doumas, B.T., Watson, W.A., Biggs, H.G., Clin. Chim.Acta. 1971; 31: 87.

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

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