AGD

CliniPak

ALBUMIN

(BCG)

Code	Pack Size
AGDSP-AL160	8 x 20mL
AGDSP-AL144	8 x 18 mL
AGDSP-AL184	8 x 23 mL

INTENDED USE

Albumin is a reagent set for in vitro quantitative determination of Albumin concentration in serum or plasma.

CLINICAL SIGNIFICANCE

The major proteins seen in the serum are albumin and globulin, the later being primarily α1 and α2 globulin, β-globulin, γ-globulin. Albumin accounts for more than 50% of the total serum proteins. Albumin is the main contributor to the plasma osmotic pressure.

Increased levels : are observed in dehydration.

Decreased levels: are observed in liver disease, nephrotic syndrome, low intake or absorption of protein, haemorrhage, severe burns and also during pregnancy.

PRINCIPLE

At pH below 5.0,Albumin is positively charged and it binds with anionic Bromocresol Green to produce blue green complex. The colour produced is measured at 630 nm (600-650 nm).The colour produced is stable for 10 minutes.

$$\text{Albumin} + \text{BCG} \xrightarrow{\text{pH (4.3)}} \text{Albumin - BCG Complex}$$

PROCEDURE

Reagent + Sample + Incubation → Measurement

(300µL) (3µL) (300sec) (630nm)

REAGENT COMPOSITION

Bromocresol Green	≈ 750 mmol/L
Succinate Buffer	≈ 350 mmol/L

REAGENT STORAGE AND STABILITY

Albumin is a single reagent ready to use.The reagent is stable till the expiry date stated on the reagent bottle label when stored at 2-8°C and protected from light.

SAMPLE

Collect sample using standard sampling tube. Preferably serum sample should be used.Heparinised plasma or EDTA plasma can also be used.Do not use hemolyzed or grossly contaminated samples.

BASIC PARAMETER

SHORT NAME	ALB
NAME	Albumin
METHOD	BCG
ASSAY	End point (two point reagent blank)
MAIN WAVE	630 nm
SUB WAVE	0
DECIMAL	2
UNIT	g/dL
R1 VOLUME	300µL
INCUBATION	36 secs
R2 VOLUME	0
SAMPLE VOLUME	3 µL
INCUBATION	0 secs
MIXING SPEED	0
REACTION TIME (Delay)	260 secs
CHECK TIME (Read)	40 secs
LINEAR RANGE	0-8
ABSORBANCE RANGE	0 - 2.5
CALIBRATION TYPE	SINGLE SPOT LINEARITY
DILUTION RATIO	6
SAMPLE VOLUME	50

*Enter calibrator value as per the lot of calibrator and method.

PERFORMANCE CHARACTERISTIC

LINEARITY

Reagent is linear up to 8 g/dL.

Dilute the sample appropriately and re-assay if albumin concentration exceeds 8 g/dL.Multiply result with dilution factor.

PRECISION

Reproducibility of within run determined using quality control sera as shown below. n =15

Quality control material	Mean g/dL	SD g/dL	% CV
Low Control serum	3.97	0.036	0.91
High Control serum	2.97	0.016	0.55

REFERENCE NORMAL VALUE

3.8 - 5.4 g/dL

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

REFERENCES

- Doumas B.T. Watson,W.A. And Biggs, H.G. Clin. Chem, Acta 31,87(1971)
- Webster, D.Clin.Chem.23,663(1977)

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ISO 13485:2016 ISO 9001:2015

EU REP

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