ALBUMIN BCG

Diagnostic reagent for determination of albumin concentration.

Liquid. Mono Reagent. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2010	5 x 100 mL	DM2010	990 Tests	BY2010	840 Tests	K2011	2273 Tests
A2011	5 x 50 mL	R2010	1111 Tests	BY2011	400 Tests	M2010	1515 Tests
A2012	5 x 25 mL	R2011	370 Tests	N2010	758 Tests	M2011	909 Tests
T2010	4091 Tests	S2010	1745 Tests	N2011	424 Tests	L2010	3000 Tests
T2011	1818 Tests	S2011	1091 Tests	K2010	3182 Tests	L2011	1600 Tests

INTENDED USE

The test is applied for the quantitative determination of albumin in serum or EDTA plasma.

TEST PRINCIPLE

In citrate buffer albumin forms with green bromocresol (BCG) a colored compound with color intensity proportional to the albumin concentration present in the sample.

More specific results are obtained if the reaction is timed and read after a short period from mixing of the sample and the reagent. The blue-green color produced in the reaction is measured at 630 nm and its intensity is proportional to the concentration of albumin in the sample.

TEST PARAMETERS

Method : Colorimetric, End Point, Increasing Reaction, BCG
Wavelength : 628 nm (580-630)
Temperature : Room temperature
Sample : Serum or EDTA plasma
Linearity : 0.2 g/L - 8 g/dL (80 g/L)

REAGENT COMPOSITION

Components	Final Concentration
Bromcresol Green	≤ 0.3 mmol/L
Buffers, Stabilizers	

REAGENT PREPARATION

The reagent is ready for use.

REAGENT STABILITY AND STORAGE

Once opened vials (reagent 1) are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

Avoid exposing the Albumin Reagent to strong sunlight. When read against a water blank, if the absorbance of the reagent at 630 nm is higher than 0.400, do not use.

SAMPLE

Samples are collected by standard procedures.
Albumin in serum is stable for 2 months at 20 - 25°C, 1 months at 2-8ºC and 3 months at -20°C.

Use preferably clear, unhemolyzed serum or EDTA plasma.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{A\ sample}{A\ standard} \times \text{concentration of standard}$$

= albumin in sample (g/dL)

Unit Conversion
g/dL x 10 = g/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Adult Men : 4.2-5.5 gr/dL
Adult Women : 3.7-5.3 gr/dL

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used.
We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The assay requires the use of an Albumin Standard or an Albumin Calibrator. We recommend:

ARCHEM Standard
Cat.No. A2290 (Conc.4.0 g/dL)

Any commercially available Standard or Calibrator suitable for this method may be used.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 0.2 g/dL

High Linearity: The assay is linear to 8 g/dL. Samples with albumin concentrations higher than 8 g/dL should be diluted with physiological saline (150 mmol/L sodium chloride in water) and assayed again; multiply results by dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	CV	SD	n
3.37 g/dL	0.04%	1.10	10
3.34 g/dL	0.04%	1.30	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	CV	SD	n
3.36 g/gL	0.04%	1.00	20
3.35 g/dL	0.07%	2.00	20

Sensitivity (LOD) (Based on CLSI EP17 document): The detection limit of the test is 0.1 g/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Methods comparison: A comparison between Archem product and a commercially available product gave the following results:

Albumin Archem = x
Albumin competitor = y
n = 73
$y = 1.009x - 0.195$ g/dl $r^2 = 0.956$

Interferance: Hemoglobin over than 10 gr/dL in grossly hemolyzed samples will interfere with the assay. Heparin has been reported to interfere with albumin determination by dye binding methods. Elevated Bilirubin over than 55 mg/dL and marked lipemia over than 1900 mg/dL may have a slight effect on the accurate determination of albumin.
Young et al. has published a comprehensive list of drugs and substances which may interfere with in vitro diagnostic assays, including the determination of albumin.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

BCG : Bromocresol
CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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