MEDICA

IVD CE

REF 10218-4 4 X 39 mL

ALBUMIN (ALB)

Wedges each contain a usable volume of 39 mL of reagent.

INTENDED USE

The EasyRA® ALB reagent is intended for the quantitative determination of albumin in human serum or plasma (with lithium heparin as anticoagulant), using the MEDICA "EasyRA Clinical Chemistry Analyzer." Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.
For *in vitro* diagnostic use only. For professional use only.

SUMMARY AND EXPLANATION

Elevated serum albumin is seldom encountered and it is usually a result of dehydration. Some of the causes of low levels of serum albumin are malnutrition, a decreased synthesis in liver diseases, proteinuria in the nephritic syndrome, loss or decreased absorption in gastrointestinal diseases, carcinomatosis, congestive heart failure, losses from extensive skin lesions such as diffuse dermatitis and burns.[1, 2]

PRINCIPLE OF THE PROCEDURE

The Albumin reagent uses the bromcresol green reagent described by Rodkey[3], later by Doumas, Watson, and Biggs.[4]
The blue-green color produced in the reaction is measured at 600 nm with a blanking wavelength of 700 nm. The color intensity is proportional to the concentration of Albumin in the sample.

REAGENT

Bromocresol green	18.8 mg/dL
Citrate buffer, pH 4.2	
Surfactant, preservative	

Precautions

1. Good laboratory safety practices should be followed when handling any laboratory reagent. (CLSI, GP17-A2).
2. The reagent contains less than 0.1% sodium azide, which may react with lead and copper plumbing to form highly explosive metal azides. Refer to the Safety Data Sheet for risk, hazard and safety information.
3. As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.
4. Do not use washed cuvettes.

INSTRUCTIONS FOR REAGENT HANDLING, STORAGE AND STABILITY

The reagent is ready to use as supplied. Unopened reagent is stable until the expiration date listed on the label if stored at 4°-25°C. Opened reagent is stable until the expiration date listed on the label if stored at 2°-8°C, or on-board in the refrigerated reagent area of the Medica EasyRA Chemistry Analyzer, for the number of days programmed on the RFID chip on the reagent wedge. Do not use the reagent if it is turbid or cloudy or if it fails to recover known serum control values.

SPECIMEN COLLECTION AND STORAGE / STABILITY

Clear unhemolyzed serum or plasma should be used. Lithium heparin coated tubes may be used for plasma collection. Serum ALB is stable for 7 days at 20 – 25°C and 1 month at 2 – 8°C.[5]

PROCEDURE

Materials Provided

Medica ALB Reagent Wedge, REF 10218

Additional materials required

Medica EasyCal Chemistry, REF 10651
Medica EasyQC® Chemistry/Electrolytes – Level A, REF 10793
Medica EasyQC Chemistry/Electrolytes – Level B, REF 10794
Medica Precision Test Dye Wedge, REF 10764
Medica Cleaner Wedge – Chemistry & ISE, REF 10660 *or*
Medica Cleaner Wedge – Chemistry, REF 10661

Instructions for Use
The reagent is ready to use as supplied. Remove the cap and place the reagent in the EasyRA analyzer reagent tray located in the reagent area. When used this way, the reagent is stable on-board in the refrigerated reagent area of the EasyRA Analyzer for the number of days programmed on the RFID chip on the reagent wedge (60 days maximum) or when removed and stored refrigerated at 2°-8°C (capped) after first opened.

Note: Check inside the neck of the wedge for foam after removing the cap and placing the wedge on the EasyRA Analyzer. If there is foam, remove it with a swab or a disposable pipette before performing the test.

Calibration
Medica EasyCal Chemistry (REF 10651) is recommended for the calibration of the assay. The calibration interval (60 days maximum) is programmed on the RFID chip on the reagent wedge. Recalibration is required whenever there is a change in reagent lot number or if a shift in quality control values occurs.

Quality Control
It is recommended that two levels of human serum based controls (normal and abnormal) be run with the assay daily whenever patient testing is performed and with each reagent lot change. Failure to obtain the proper range of values in the assay of control material may indicate reagent deterioration, instrument malfunction, or procedural errors. The laboratory should follow local, state and federal quality control guidelines when using quality control materials.

Results
After completion of the assay, the EasyRA Analyzer calculates the ALB concentration based on the following equation:

$$\text{ALB (g/dL)} = \frac{[(A_U - A_{Blk})_{600} - (A_U - A_{Blk})_{700}]}{[(A_C - A_{Blk})_{600} - (A_C - A_{Blk})_{700}]} \times \text{Cal Value}$$

Where A_U and A_C are the absorbance values of the unknown and the calibrator, respectively; A_{Blk} is the absorbance of the reagent blank; and "Cal Value" is the concentration of Albumin in the calibrator (g/dL).

Expected Values[5]
The reference range for ALB in serum is as follows:

Adult: 3.8-5.1 g/dL

These values are guidelines. It is recommended that each laboratory establish its own range of expected values since differences exist among instruments, laboratories and local populations.

Procedural Limitations (e.g., if sample is above assay range)
Avoid using hemolyzed serum or plasma samples.

The Medica EasyRA Chemistry Analyzer flags any result above 7 g/dL as Linearity High "LH". If the "Re-run" icon is selected by the operator, the sample may be re-tested using one half (1/2) the sample volume. The retest results are calculated to reflect the use of the smaller sample volume. This will extend the reportable range of the ALB test to 14 g/dL.

PERFORMANCE CHARACTERISTICS[6]

Reportable Range
The reportable range is 0.4 to 7 g/dL. Extended range is 0.4 to 14 g/dL when half of the sample is used (1:1 dilution).

Inaccuracy / Correlation (CLSI, EP9-A2)
The following table lists the data obtained in a comparison of the Medica Reagent for ALB (y) on the EasyRA Analyzer to the performance of a similar ALB reagent (x) on the Roche COBAS MIRA* Analyzer. The data shown below represents single determinations on the EasyRA Analyzer vs. the average of two replicate values obtained on the COBAS MIRA Analyzer.

Number of samples	43	Range of Samples	0.5 to 6.5 g/dL
Slope	0.9651	y Intercept	- 0.0945
Correlation Coefficient	0.9859	Regression Equation:	Y = 0.9651*X – 0.0945

** Cobas Mira is a registered trademark of Roche Diagnostics, INC., Indianapolis, IN.*

The following table lists the data obtained in a comparison of matched serum (x) and Li-heparinized plasma (y) samples using the Medica reagent for ALB on the EasyRA Analyzer. The data below represents a single plasma determination vs. the average of two replicate serum values.

Number of Samples	71	Range of Samples	0.4 to 6.6 mg/dL
Slope	1.0074	y Intercept	-0.0283
Correlation	0.9937	Regression Equation	Y = 1.0074*X – 0.0283

Imprecision (CLSI, EP5-A2)
Duplicate measurements of each of three levels of QC material were tested twice a day for 20 days. Both within-run precision and total precision were determined from these data.

Within run imprecision:

QC Level g/dL	Within Run SD g/dL	Within Run CV %
4.6	0.03	0.6
3.1	0.03	0.9
2.7	0.03	1.2

Total Imprecision:

QC Level g/dL	Total Imprecision SD g/dL	Total Imprecision CV %
4.6	0.05	1.2
3.1	0.03	0.0
2.7	0.03	1.3

Linearity (CLSI, EP6-A)
Linear from 0.4 to 7.0 g/dL, based on the linear regression Y = 1.0462*X – 0.2886.

Limit of Blank (LOB):	0.00 g/dL	(CLSI, EP17-A)
Limit of Detection (LOD):	0.02 g/dL	(CLSI, EP17-A)

Interfering Substances (CLSI, EP7-A)
Less than 10% interference was classified as “no significant interference.”
There is significant interference at hemoglobin levels above 500 mg/dL. Avoid using hemolyzed serum or plasma samples.
No significant interference was found in levels up to 25 mg/dL of bilirubin.
No significant interference was found in levels up to 1350 mg/dL of triglycerides (using Intralipid*).

**Intralipid is a registered trademark of Pharmacia AB, Clayton, NC.*

Young provides a list of drugs and other substances that interfere with clinical chemistry tests.[7]

References

1 Burtis CA, Ashwood ER. *Tietz Textbook of Clinical Chemistry, 2nd ed.* Philadelphia, PA: WB Saunders Co.; 1994: 700-704.
2 Wolf RL. *Methods and Techniques in Clinical Chemistry*. New York, NY: Wiley-Interscience; 1972.
3 Rodkey EL. *Clin. Chem*. 1965; 11: 478.
4 Doumas BT, Watson WA, Biggs HG. Albumin standards and the measurement of serum albumin with bromocresol green. *Clin Chim Acta*. 1971; 31: 87-96.
5 Doumas BT, Biggs HG: *IN Standard Methods of Clinical Chemistry* Vol 7. Academic Press, New York, 1972, p 175.
6 Data on file at Medica.
7 Young DS. Young’s Effects on-line. *Effects of Drugs, Physiology, Preanalytical variables and herbs on Clinical Laboratory Tests*. AACC www.fxol.org.

EasyRA Assay Parameters (ALB)

Primary Wavelength (nm)	600
Secondary Wavelength (nm)	700
Reaction Type	Endpoint (2)
Reagent Direction	Increase
Reagent Blank	Yes (with each calibration)
Sample Blank	No
Blank high Abs. limit	0.5
Reaction Time	3.6 min.
Calibration interval (maximum)	60 days
Reagent on-board stability	60 days

Serum/Plasma

Sample volume (µl)	2.0
Diluent Volume (µl)	20
Reagent Volume (µl)	160
Decimal Places (default)	1
Units (default values)	g/dL
Dilution Factor	1:1 (to extend measuring range)
Linearity	0.4 to 7.0 g/dL

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