ENVOY® 500 ALBUMIN REAGENT KIT

Product no. 55225

For *in vitro* diagnostic use

CAUTION : Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (Rx ONLY)

INTENDED USE

Envoy® 500 ALBUMIN Reagent is for the quantitative *in vitro* diagnostic determination of albumin in human serum and plasma on Envoy 500 Series Analyzers. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

It is not intended for use in Point of Care settings.

CLINICAL SIGNIFICANCE [1-4]

Albumin, synthetised primarily by the liver, represents approximately 50% of plasma proteins. Because of its small size and its high plasmatic concentration, albumin is the major protein component of most extra-vascular body fluid, including CSF, interstitial fluid, urine and amniotic fluid. Albumin's primary function is the maintenance of colloidal osmotic pressure in both extravascular and vascular spaces, with continuous equilibration. Albumin also binds and transports a large number of compounds (ions, free fatty acids, bilirubin, drugs...). Albumin is a mobile reserve of amino acids.

Increased levels of albumin are present only in acute dehydratation or hemodilution. Hypoalbuminemia is seen in a multitude of diseases bound to different pathological states: acute and chronic inflammation; decreased synthesis: hepatic insufficiency, sever malnutrition, analbuminemia...; increased loss: nephritic syndrom, gastrointestinal loss, sever and large burns, bedsore...; increased catabolism: fever, hyperthyroidism....

METHODOLOGY [5-7]

Colorimetric determination of albumin using bromocresol green at pH 4.20: (Colorimetric - Bromocresol green (BCG)):

$$\text{Albumin} + \text{BCG} \xrightarrow{pH = 4.20} \text{Albumin-BCG complex}$$

Albumin-BCG complex absorbs at 630 nm. The final absorbance at this wavelength is proportional to the concentration of albumin in the sample.

REAGENTS

COMPOSITION

Albumin Reagent contains 87 mmol/L Succinate buffer, pH 4.20 ; 0.2 mmol/L Bromocresol green ; 7.35 mL/L Brij 35.

WARNINGS AND PRECAUTIONS

- This reagent is for professional *in vitro* diagnostic use only.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contaminations.
- For more information, Safety Data Sheet (SDS) is available on request for professional user.
- Dispose of contents in accordance with all local, state and federal regulations.

PREPARATION

Albumin Reagent is ready for use on the Envoy 500 Analyzer as packaged.

STORAGE AND STABILITY

Store this reagent at 2 to 25 °C and protected from light. Do not freeze. Unopened reagents are stable to the expiration dates on the bottle labels. The reagent is stable for 28 days onboard the Envoy 500 Analyzer.

SPECIMENS [1-2]

COLLECTION AND STORAGE

Fresh unhemolyzed serum or lithium heparinized plasma is the preferred specimen. Do not analyze whole blood.

Collect specimens by venipuncture according to accepted clinical protocol.

For best results, use only fresh specimens. Albumin in samples is stable at 2-8 °C less than 72 hours. Stored at < -20 °C, samples are stable for 6 months. For a longer storage, freeze samples at -70 °C.

PROCEDURE

MATERIALS PROVIDED

The Envoy 500 Albumin Reagent Kit includes the following components:

8 x 49.0 mL boats of Envoy 500 Albumin Reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Envoy 500 Serum Calibrator (product no. 55111).
- Envoy 500 Serum Controls (product no. 55131).
- Analyzer specific consumables
- General Laboratory Equipment.

REAGENT INSTALLATION AND USE

Program the instrument using the application parameters and programming instructions provided at the end of this Instructions For Use. Refer to the Operator Manual for additional information on installing reagents and programming the analyzer, and running samples, calibrators and controls.

The Envoy 500 Albumin Reagent is ready to use as packaged. Do not remove the caps from the bottles until you are ready to install the reagent on the analyzer. Before installing, mix the reagents by gently inverting the reagent boats several times. Record the installation date on the label and insert the unit into the designated position on the reagent tray. Let the reagent equilibrate on the instrument for at least 30 minutes before use.

CALIBRATION

Calibrate the instrument after loading new reagent lot, after maintenance and whenever quality control results fall outside established limits. Under typical use conditions, calibration factors for this test are valid for 28 days. Refer to the Operator Manual for calibration procedures.

QUALITY CONTROL

Quality control requirements should be established in accordance with local, state and/or federal regulations or accreditation requirements.

Assay at least two levels of serum control daily. Serum Controls for Envoy 500 level 1 and level 2 may be used. Controls should also be assayed after performing a reagent blank, calibrating, maintaining the instrument and after loading a new reagent unit.

Controls may be assayed more frequently based on laboratory workflow and the discretion of the user.

CALCULATIONS

All calculations are performed by the instrument.

To calculate the result in SI units (g/L), multiply the result in conventional units (g/dL) by 10.

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LIMITATIONS

Do not analyze whole blood. Only calibrate with the Envoy 500 Serum Calibrator (product no. 55111). Use only acceptable specimens as described under Collection and Storage. Do not report results outside of the usable range shown below. Refer to the Interfering Substances section for possible sources of chemical interference.

PERFORMANCE CHARACTERISTICS

MEASURING RANGE

Determined according to CLSI[8] EP6-A protocol, the measuring range is from 1.6 to 6.0 g/dL (16 to 60 g/L)

LIMIT OF DETECTION (LOD) AND LIMIT OF QUANTIFICATION (LOQ)

Determined according to CLSI[9] EP17-A protocol, the LoD is 0.04 g/dL (0.4 g/L) and LoQ is 0.50 g/dL (5 g/L).

EXPECTED VALUES [1]

Published albumin reference ranges are listed below. Use these ranges only as guides. Each laboratory should establish its own reference ranges.

Reference Range	Conventional Units	SI Units
Serum/plasma		
Adults	3.5 - 5.2 g/dL	35 - 52 g/L
60-90 years	3.2 - 4.6 g/dL	32 - 46 g/L
> 90 years	2.9 - 4.5 g/dL	29 - 45 g/L

In ambulatory patients, values average ~0.3 g/dL higher.

PRECISION

Determined according to CLSI[10] EP5-A2 protocol.

Sample	n	mean g/dL	Within-run CV (%)	Total CV (%)
Level 1	80	2.49	1.7	2.9
Level 2	80	3.68	1.2	2.7
Level 3	80	4.83	1.5	2.6

☛METHOD COMPARISON

A comparative study has been performed between an Envoy 500 Analyzer and an FDA-approved system equipment (BCG method) on 103 human serum samples according to CLSI[11] EP9-A2 protocol.
The sample concentrations were between 1.68 and 5.88 g/dL (16.8 and 58.8 g/L).

The parameters of the linear regressions are as follows :
Correlation coefficient: (r) = 0.993
Linear regression: y = 1.003 x - 0.08 g/dL (0.8 g/L)

INTERFERING SUBSTANCES

Studies have been performed to determine the level of interference from different compounds according to CLSI[12] EP7-A2 protocol. Recovery is within ± 10% of initial value of albumin concentration of 3.50 g/dL and 5.00 g/dL.

Unconjugated Bilirubin:	No significant interference up to 30.0 mg/dL (513 µmol/L).
Conjugated Bilirubin:	No significant interference up to 29.5 mg/dL (504 µmol/L).
Hemoglobin:	No significant interference up to 500 mg/dL.
Triglycerides:	No significant interference up to 3000 mg/dL (33.90 mmol/L).
Ascorbic acid:	No significant interference up to 20 mg/dL (1136 µmol/L).
Acetaminophen:	No significant interference up to 30 mg/dL.
Acetylsalicylic acid:	No significant interference up to 200 mg/dL.
γ-globulin:	No significant interference up to 1500 mg/dL.

In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[13]

Other compounds may interfere.[14,15]

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10. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition*. CLSI (NCCLS) document EP5-A2 (2004), **24** (25).
11. *Method Comparison and Bias estimation Using Patient Samples; Approved Guideline—Second Edition*. CLSI (NCCLS) document EP9-A2 (2002), **22** (19).
12. *Interference Testing in Clinical Chemistry ; Approved Guideline—Second Edition*. CLSI (NCCLS) document EP7-A2 (2005), **25** (27).
13. Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.
14. Young, D.S., Effects of preanalytical variables on clinical laboratory tests, 2nd edition, AACC Press (1997).
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GLOSSARY OF SYMBOLS

CONT	Contents		Manufacturer	REF	Catalog No.
LOT	Batch Code		See instruction for use		Use by
OPENED	Date opened / Installation date	IVD	*In vitro* diagnostic device		Temperature Limitation
STAB DAYS	Number of days onboard stability	R	Reagent		

☛ : Modification from previous version

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ELITechGroup CLINICAL SYSTEMS

APPLICATION PARAMETERS

PRIMARY PARAMETERS

Code	ALB
Bar-Code	Active
Code for Bar-Code	338
Test Methodology	Bromocresol Green
Method	End Point
Kind of Process	Linear
1st Filter	630
2nd Filter	700
Reaction direction	Increasing

REAGENTS

Number of reagents	1
Reagent 1 Volume µL	298
Concentrated	Inactive
Reagent 2 Volume µL	N/A
Concentrated	Inactive

SAMPLE

	Serum	Urine
Name	Albumin	N/A
Sample µL	2	N/A
Pre-Dilution 1:	1	N/A
Post-Dilution 1:	1	N/A

TIMES

Sample Starter	Inactive
Delay Time	0
Reading Time	30
Reagent 1 Incubation Time	24
Reagent 2 Incubation Time	N/A

CHECK PARAMETERS

Reagent Limit (mABS)	400
Curve Acceptance (%)	100

RE-RUN SERUM

Test Limit (Conc)	6	
Low Test Limit (Conc)	0.04	
Initial ABS (mABS)	N/A	
Final ABS (mABS)	2400	
Max ABS Delta (mABS)	9999	
Prozone Check	Inactive	
Normal Range	Min	Max
Man	[User defined]	
Woman	[User defined]	
Child	[User defined]	
Re-run hyperactive	Inactive	
Re-run pathological	Inactive	

RE-RUN URINE

Test Limit (Conc)	N/A	
Low Test Limit (Conc)	N/A	
Initial ABS (mABS)	N/A	
Final ABS (mABS)	N/A	
Max ABS Delta (mABS)	N/A	
Prozone Check	Inactive	
Normal Range	Min	Max
Man	[User defined]	
Woman	[User defined]	
Child	[User defined]	
Re-run hyperactive	Inactive	
Re-run pathological	Inactive	

SECONDARY PARAMETERS

1st Unit Serum	g/dL
2nd Unit Serum	Inactive
1st Unit Urine	N/A
2nd Unit Urine	Inactive
Dynamic Blank	Inactive
Needle washes	[From Settings Table]
Cuvette washes	[From Settings Table]
Special Wash	[From Settings Table]
Instrumental Factor	1.000
Shift	0.000
Reagent Blank	Every Day
Decimals	2

STANDARD PARAMETERS

Factor	[Determined by calibration]
Minimum	4
Maximum	6.5
Number of Samples	1
Max Var. (%)	10
Timed re-run	Inactive
N. replicates	3
Reagents ABS	[Determined by Envoy]
Pos.	[From Settings Table]
Conc.	[From calibrator labeling]
ABS	[Determined by Envoy]
% from last calibration	100

PROGRAMMING INSTRUCTIONS

Detailed instructions for programming reagent parameters are provided in the Envoy 500 Operator Manual and Envoy 500 Settings Table.

If the Envoy 500 Chemistry System is not pre-programmed, a Albumin code must first be added before the parameters can be entered. On the menu bar, select «Test → Test Directory.» A new window will open up listing all the codes for the tests that are installed on the instrument. Click on the «New Code» button, type «ALB» into the Code field and select «Save.»

To program the application parameters, check the box next to the code for the ALB test, and select the «Parameters» button located at the bottom of the window. To program standard information, click the «Standards» button located at the bottom of the window.

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