MICROALBUMIN (uALB)

TURBIDIMETRY

Intended use:
Albumin in the urine sample causes agglutination of the latex particles coated with anti-human albumin. The agglutination of the particles is proportional to the albumin concentration and can be measured by turbidimetry.

Composition:

A. Reagent: Borate buffer 0.1 mol/L, sodium azide 0.95 g/L, pH 10.0.
B. Reagent: Suspension of latex particles coated with anti-human albumin antibodies, sodium azide 0.95 g/L.
S. Albumin Standard: Human albumin. Albumin concentration is given on the label. The concentration value is traceable to the ERM DA-470 reference standard (Institute for Reference Materials and Measurements, IRMM). Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

Preparation and stability:
R1: Ready for use.
R2: Ready for use.
Mix reagent R2 well before first use and once weekly!
Unopened kit components: Up to the expiration date at +2°C to +8°C
R1: 90 days opened and refrigerated on the analyser
R2: 90 days opened and refrigerated on the analyser

Specimen:
Urine collected by standard procedures. Urine should be centrifuged before analysis. Albumin in urine is stable for 7 days at 2-8ºC.

Limitations - interference:
Criterion: Recovery within ±10% of initial value.
Icterus: No significant interference up to an index I of 26 (approximate conjugated and unconjugated bilirubin concentration: 26 mg/dl).
Hemolysis: No significant interference up to an index H of 1000 (approximate haemoglobin concentration: 1000 mg/dl).
Lipemia (Intralipid): No significant interference up to an index L of 1000 (approximate triglycerides concentration: 2000 mg/dl). There is poor correlation between turbidly and triglycerides concentration. Rheumatoid factors < 180 lU/l do not interfere.

Measuring/reportable range:
0.9-200 mg/L
At higher concentrations, dilute the sample with 0.9% NaCl (e.g. 3 + 1). Multiply the result by the appropriate factor (e.g. 2).

Expected values:
Adults: Up to 15 mg/L
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes the uALB results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

Analytical sensitivity (lower detection limit)
Detection limit: 0.9 mg/L
The lower detection limit represents the lowest measurable uALB concentration that can be distinguished from zero. It is calculated as three standard deviations of 21 replicates of the lowest standard.

Quality Control:
Human Control Serum:

BIOANALYTIC PROTEIN CON L1	1 x 1 ml	#B10844
BIOANALYTIC PROTEIN CON L2	1 x 1 ml	#B10845

Calibration:
Standardization: This uALB method was calibrated against an international standard defined for uALB.
S1: BIOANALYTIC uALB CAL. SET

Testing procedure:
Applications for automated systems are available on request.
Materials provided
Working solutions as described above Additional materials required

Manual procedure:	
Wavelength:	530 nm
Zero adjustment:	against reagent blank
	Sample/ Calibrator
Sample/Calibrator	10 µl
R1	800 µl
R2	200 µl
Mix, read absorbance A1 after 9 sec. Incubate 2 min. and read absorbance A_2.	
Calculation:	
A = [(A_2 – A_1) sample or Calibrator] - [(A2 - A,) blank]	
The concentration of uALB in patient sera has to be calculated from A using linear method For zero value is recommended to use saline solution (0.9%)	

Imprecision:
Reproducibility was determined using human samples and controls in an internal protocol (n = 21). The following results were obtained:

Repeatibility (within run):

Mean concentration	CV	n
18 mg/L	2.4 %	20
57 mg/L	2.2 %	20

Reproducibility (run to run):

Mean concentration	CV	n
18 mg/L	5.7 %	25
57 mg/L	3.6 %	25

Method comparison:
A comparison of the BIOANALYTIC uALB (y) with a commercial obtainable assay (x) gave the following result (mg/L). y = 1.07 x + 2.01; r = 0.99

Literature:

1. Cambiaso CL, Collet-Cassart D, Lievens M. Immunoassay of low concentrations of albumin in urine by latex particle counting. Clin Chem 1988; 34(2):416-418
2. Medcalf EA, Newman DJ, Gorman EG, Price CP. Rapid, robust method for measuring low concentrations of albumin in urine. Clin Chem 1990; 36(3):446-449
3. Harmoinen A, Ala-Houhala I, Vuorinen P. Rapid and sensitive immunoassay for albumin determination in urine. Clin Chim Acta 1985 15;149(2-3):269-74
4. Bernard A, Lauwerys R. Latex immunoassay of urinary albumin. J Clin Chem Clin Biochem 1983; 21(1):25-30
5. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2005.
6. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
7. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press,2001.

Order information (Cat No.) :

CC525	SH525	BUAL125	B25245	B31245	B35245
OL525	CR525	B21245	B27245	B32245	B36245
AB525	BUAL500	B22245	B28245	B33245	B37245
KL525	BUAL250	B24245	B30245	B34245	B80245

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SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions

ISO 9001:2015
ISO 13485:2016