ALBUMIN (Microalbumin)

Diagnostic reagent for determination of albumin (urine) concentration.

Liquid. Dual Reagents. 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
8A700	450 mL	DMA72	100 mL	M3A71	200 mL	RD700	150 mL
A2295	125 mL	HN355	300 mL	M4A70	350 mL	TBMA70	350 mL
BB140	200 mL	KMA70	600 mL	M4A71	175 mL	TMA70	350 mL
BY700	450 mL	KMA71	300 mL	MDA70	250 mL		
BZ2150	180 mL	LM071	80 mL	MMA70	350 mL		
DMA70	350 mL	LMA70	200 mL	MMA71	175 mL		
DMA71	312,5 mL	M3A70	250 mL	PL2285	120 mL		

INTENDED USE

The test is applied for the quantitative determination of albumin (urine) concentration in urine.

Urinary albumin concentration values provide a good indicator of changes in glomerular permeability, as occur in a number of renal disease.

Diabetic nephropathy is characterized by an early hyperfiltration stage resulting in small increases in urinary albumin excretion. That is why the measurement of urinary albumin is considered a clinically important indicator of deteriorating renal function in diabetic subjects. Urinary albumin excretion is also monitored in hypertensive patients to identify the development of significant nephropathy.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

TEST PRINCIPLE

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.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 540 nm
Temperature : 37°C
Sample : Urine
Linearity : 1mg/L- 250 mg/L
(0,1mg/dL- 25 mg/dL)

REAGENT COMPOSITION

Reagent 1:
Borate buffer ≤ 0.12 mol/L,
Sodium azide ≤ 1.00 g/L, pH 10.0.

Reagent 2:
Suspension of latex particles coated with anti-human albumin antibodies,
Sodium azide ≤ 1.00 g/L.

S. Albumin Standard: Human albumin.
Albumin concentration is given on the label. Concentration value is traceable to the Standard Reference Material BCR 470 (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.

REAGENT PREPARATION

Working Reagent: Pour the contents of Reagent B vial into Reagent 1 bottle. Mix thoroughly. Reagents are stable for 15 days at 2-8ºC.

Smaller Working Reagent volumes can be prepared by mixing: 1 mL of Reagent 2 + 4 mL of Reagent 1. Shake the Latex vial before pippeting.

Albumin Standard (S): Reconstitute with 1.00 mL of distilled water. Standards are stable for 1 month at 2-8ºC.

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Store at 2-8ºC.
Reagents and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

Reagents: absorbance of the blank over 1.200 at 540 nm.

Standard: Presence of moisture.

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.

SAMPLE

Urine is collected by standard procedures. Urine should be centrifuged before analysis. Albumin in urine is stable for 7 days at 2-8ºC, 2 weeks at 4°C (for timed or 24h samples), maximum 6 days at 4°C (for spot samples) and approximately 5 months at -70°C.

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.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

The albumin concentration in the sample is calculated using the following general formula:

$$\frac{(A2 - A1)\ \text{Sample}}{(A2 - A1)\ \text{Standard}} \times C\ \text{Standard}$$

= C Sample (mg/L)

REFERENCE INTERVAL (NORMAL VALUES) *

Urine,
Adults: Up to 15 mg/L

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

QUALITY CONTROL AND CALIBRATION

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 25 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: 1 mg/L (0,1 mg/dL albümin)

High Linearity: 250 mg/L (25 mg/dL) albumin. For higher values dilute sample 1/3 with distilled water and repeat measurement. Linearity may considerably vary depending on the instrument used.

Linearity may considerably vary depending on the instrument used.

Precision Studies:

Repeatibility (within run) (Intra-assay)

Mean concentration	CV	n
18 mg/L	2.4%	40
57 mg/L	2.4%	40

Reproducibility (run to run) (Inter-assay)

Mean concentration	CV	n
18 mg/L	5.7%	40
57 mg/L	3.6%	40

Sensitivity (LOD): The detection limit of this test is 3 mg/L.

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.

Prozone effect: falsely low values are obtained when albumin is present in the sample at a concentration higher than 700 mg/L.

Interferences: Bilirubin (20 mg/dL) does not interfere. Hemoglobin (1 g/L) may interfere. Other drugs and substances may interfere.

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 and controls 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. 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.

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 GLP guidelines.
R32: Contact with acids liberates very toxic gas.
EUH032: Contact with acids liberates very toxic gas.
H300: Fatal if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies products to be used together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration date
	Temperature limitation
	Consult instructions for use
	Caution
	Sufficient for

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