MICROALBUMIN II

Diagnostic reagent for determination of Microalbumin concentration.
Liquid. Dual reagents. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Pack
MH-232	80 mL
MH-232	48 mL

Changes made in the instructions for use are marked as grey.

INTENDED USE

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

TEST SUMMARY AND PROCEDURE [1, 2, 3, 4, 5]

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.

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 turbidimetrically.

Clinical diagnosis should not be made only with the findings of test results, integration of the laboratory data should be used in clinical diagnosis as well.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 540 nm
Linearity : 270 mg/L (27 mg/dL)

REAGENT COMPONENTS

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.

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE [6]

Reagents are stable at +2/+8˚C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

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 24 hour samples),
6 days at 4°C (for spot samples),
5 months at -70°C.

REFERENCE INTERVAL (NORMAL VALUES) [7]

Urine
Adults : Up to 15 mg/L

It is recommended that each laboratory establish its own normal range.

Reference interval has been verified by using CLSI EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

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

Microalbumin Control Level I
Ref.No: VT-015

Microalbumin Control Level II
Ref.No: VT-016
The assay requires the use of a Micraolbumin Calibrator. We recommend:

Microalbumin Calibrator
Ref.No: VT-017

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 30 days.

If controls are not within acceptable limits, calibration is required and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

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

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of the test detection is 1 mg/L.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ≤ 20%]**:**[8] 2 mg/L (0.2 mg/dL albumin)

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 270 mg/L (27 mg/dL).

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:[9]

Repeatibility (Within Run) (Intra-Assay)

Mean Concentration	CV%	n
13.2 mg/Lö	1.20	40
34.4 mg/L	1.90	40

Repeatibility (Day to Day) (Inter-Assay)

Mean Concentration	CV%	n
18.0 mg/L	3.30	40
60.0 mg/L	2.00	40

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Prozone Effect: No prozone effect has been observed up to 700 mg/L value which is tested for Microalbumin.

Interference:[3, 4, 12]
No significant interactions were observed for hemoglobin, conjugated bilirubin up to the interferent concentration given.

Hemoglobin	: ≤ 1.0 g/L
Bilirubin	: ≤ 20 mg/dL

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

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

WARNINGS AND PRECAUTIONS

IVD**:** For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032	:Releases a very toxic gas if contacts with acid.
H317	:May cause allergic skin reaction.

Precaution

P280	:Use protective gloves / clothes / glasses / mask.
P264	:Wash your hands properly after using.
P272	:Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352	:Wash with plenty of water and soap if it contacts with skin.
P333+P313	:Seek medical help if it irritates your skin or develops rash.
P362+P364	:Remove contaminated clothes and wash properly before using.

Disposal

P501	:Dispose the vials and contents according to the local regulations.

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Archem Sağlık Sanayi ve Tic. A.Ş. . (With official contract based manufacturing agreement with Validity Sağlık Hiz. Sanayi A.Ş. Company)
Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
Bağcılar/İstanbul/Turkey
Tel: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr **www.archem.com.tr**
info@validity.com.tr **www.validity.com.tr**

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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 Limits
	Consult Instructions for Use
	Caution
	Number of Tests