MICROALBUMIN
Multi-Purpose (MPR) Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL501MA	1 x 50 ml 1 x 10 ml	MICROALBUMIN - 1 MICROALBUMIN - 2	2 - 8°C
GL521MA	5 x 50 ml 5 x 10 ml	MICROALBUMIN - 1 MICROALBUMIN - 2	2 - 8°C
GL531MA	2 x 50 ml 2 x 10 ml	MICROALBUMIN - 1 MICROALBUMIN - 2	2 - 8°C

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Microalbumin in urine on automated and semi-automated analysers.

SUMMARY AND EXPLANATION:

Urinary albumin excretion of between 30 and 300 mg/day is defined as microalbuminuria. This is an abnormal level of protein but is less than that detected on a routine urine dipstick. Routine screening for the detection of microalbuminuria in diabetic patient is an important component in the prevention of diabetic renal diseases. Diabetes, for both Type I and Type II diabetes, yearly testing of microalbumin is recommended. Many clinics now utilise the measurement of creatinine in combination with microalbumin to avoid the necessity of a 24-hour collection. The normal range being less than 30 mg/g creatinine for spot urine.

PRINCIPLE OF THE TEST: [1]

The sample is reacted with a specific antiserum to form a precipitate, which is measured turbidimetrically at 340 nm. By constructing a standard curve, the microalbumin concentration can be determined. The amount of complex formed is directly proportional to the amount of microalbumin in the sample.

Microalbumin antigen + Anti-microalbumin antibody ⟶ Antigen/antibody complex

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear colourless liquid.
Reagent 2: Pale beige liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:
Product is not hazardous under EU specification. Contain minute quantity of Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	TRIS Buffer pH 7.6	18.2 mmol/l
	Sodium Chloride	123.2 mmol/l
	PEG	< 4 %
Reagent 2	Sodium Chloride	154 mmol/l
	Anti (Human) Albumin	---
	PRESERVATIVE	---

INSTRUMENTS:

Instrument application procedures are available upon request.

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, components are stable until expiry date stated on the label.

Prepare a range of 6 standards by serially diluting Calibrator (GL966) in saline as follows:

Dilution	Neat	1/2	1/4	1/8	1/16	1/32
Factor	1	0.5	0.25	0.125	0.063	0.032

TYPE OF SPECIMEN:

Urine :
Use 1st morning urine as specimen.

Cerebral Spinal Fluid (CSF) :
Note: If the Total Protein in CSF is greater than 2000 mg/l, the CSF needs to be diluted 1/10 and the result multiplied by 10.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sampling container, with proper specimen identification. Store at 4°C and analyse no later than 2 hours after collection.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
Microalbumin Calibrator	GL966	Photometer	N/A
Microalbumin Control	GL906	General Laboratory Equipment	N/A

Assay procedure:
Wavelength: λ: 340 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	**Calibrator**	**Sample**
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	70 µl
Calibrator	----	70 µl	----
Gently mix and Incubate at 37°C Measure the Optical Density (OD1) after 5 minutes.			
Reagent 2	200 µl	200 µl	200 µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD2) after 10 minutes.			

Urine should be screened first using dip sticks. If the dip sticks indicate significant protein urea's, the sample should be diluted alternatively, a Urinary Protein method should be used.

Refer to your analyser operator's manual for instructions on instrument start-up, loading components and samples, calibration, sample-testing procedures, calculating and reporting results.

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory Q. C. Programme.

CALCULATION:

- Calculate the Δ Abs for each standard in the series and construct a calibration curve. Δ Abs = OD2 – OD1
- Calculate the Δ Abs for each sample. Determine the corresponding concentration from the calibration curve.

(Conversion factor: Qty in mg/l = Qty in mg/dl x 10)

EXPECTED VALUES[2]:

	Urine Albumin Excretion	
Condition	*mg/24hours*	*µg/min*
Normal	< 30	< 20
Microalbuminuria	30 to 300	20 to 200
Macroalbuminuria	> 300	> 200

Each laboratory should establish its own reference range. Microalbumin should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Prozone:
The system did not show prozone phenomena at least up to 1.25g/L or 1250mg/L.

Linearity:
This assay is linear across the calibration range.
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Sensitivity:
The Lowest Detectable Level was estimated at 0.3 mg/l.

Precision:

Within Run N = 20	Mean *(mg/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(mg/l)*	*SD*	*% CV*
Level 1	24.4	0.39	1.61	Level 1	24.2	0.77	3.19
Level 2	41.0	0.66	1.62	Level 2	41.5	1.02	2.45

Method Comparison:
Using 50 samples, a comparison, between this Microalbumin test (y) and another commercially available test (x), gave the following results:

y = 0.957x + 0.104	r = 1.000	Sample range: 0.5 to 491.0 mg/l

BIBLIOGRAPHY:

1. Harmoinen A, Vuorinen P, Jokela H. Turbidimetric measurement of Microalbuminuria, Clin Chem Acta 1987; 166:85-9.
2. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 428, 459 and 962.

SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
CE	CE Mark - Device comply with the Directives 98/79/EC		
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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