

R1: 1x 50 mL **REF** A-R1100003901
R2: 1x 7 mL

SUMMARY AND EXPLANATION OF THE TEST

Diabetic nephropathy, which is accompanied by irreversible kidney damage and persistent proteinuria, is a major cause of death in persons with insulin-dependent diabetes mellitus. An early sign of diabetic nephropathy are small Albumin secretions in urine, i.e. Microalbuminuria. Therefore, detection of kidney (glomerular) damage that is minimal and reversible is important.

PRINCIPLE OF THE TEST

Measurement of antigen-antibody reaction by the end-point method.

Microalbumin Reagent Kit

Code A-R1100003901

Reagent 1 (R1) - Buffer - 1 x 48.5 mL/vial

Reagent 2 (R2) - 1 x 6.5 mL/vial

Each vial is ready to use and contains:

Reagent 1:	Conc.	U.M.
Saline	9	g/L
Accelerator	/	/
Sodium azide	0,95	g/L
Reagent 2:	Conc.	U.M.
Phosphate buffered saline (pH 7.43)	/	/
Polyclonal goat anti-human Albumin (variable)	/	/
Sodium azide	0,95	g/L

Reagent Preparation:

Liquids reagents ready for use.

Storage and Stability:

If stored at 2 - 8°C avoiding direct light, the reactants remain stable until the expiration date printed on the label.

Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Do not freeze the reagents.

EQUIPMENT / ACCESSORIES REQUIRED AND NOT SUPPLIED

General laboratory equipment

Saline (9 g/L)

Calibrators and/or Control

(Pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Value is stated in the insert)

PRECAUTIONS AND LIMITATIONS

For *in vitro* diagnostic use.

Only experienced laboratory personnel should use this test and handling should be in agreement with Good Laboratory Practice (GLP).

Reagents from different lots must not be interchanged.

Safety Precautions

- Each donor unit used in the preparation of the reagents, standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA
- Do not pipet by mouth.
- Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
- Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
- Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols.
- Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
- In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components is lower than the limits reported by the current directive and following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
- All human samples must be handled and disposed of as potentially infectious materials.
- For information about safe handling, read carefully the Material Safety Data Sheet (MSDS).

Disposal of Reagents

Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

SPECIMEN COLLECTION AND STORAGE

Collect urine during 24 hours or as a random midstream sample.

If the test can not be carried out on the same day, the urine may be stored at 2 - 8°C for 48 hours.

If stored for a longer period, the sample should be frozen. The use of centrifuged urine is recommended.

Quality control

It's necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Automation

All applications not explicitly approved by ISE S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Procedures

Sample/Control/Standard: Ready for use.

Reference curve: generate a reference curve by Microalbumin standard kit Ref R-1300002001.

Use saline 9 g/L as zero point.

Method for automated instrumentation

Analyzer:	Miura Family		
Analyte Name :	Microalbumin	Ref.:	A-R1100003901
Method Code:	MAL		
Type:	Different. Sample Blk.		
Unit:	mg/L		
Filter F1:	340 nm		
Blank in calculation:	Not Used		
Step	Reaction volume	U.M.	
Sample volume:	12	µL	
Volume Reagent 1:	190	µL	
Volume Reagent 2:	30	µL	
Incubation Time	60	Sec.	
Reading Time:	300	Sec.	
Calibration	See Reference Curve		

EXPECTED VALUES

0 - 25 mg/L (IFCC)

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

PERFORMANCE CHARACTERISTICS

The performance characteristics for the Microalbumin reagents were measured on a clinical chemistry analyzer.

Measuring Range:	0 - 400 mg/L
Detection Limit:	0.7 mg/L
Hookeffect:	> 6000 mg/L
Sensitivity:	28.5 ABS units/concentration unit

Precision: [%CV]	Low	Medium	High	
	Intra-Run	0.91	0.88	1.52
	Inter-Run	2.93	0.66	0.53







Accuracy: [mg/L]	Control	Assigned	Measured
	Beckman	21.5 (18 - 25)	22.5

Specificity:	Monospecific
Interferences:	No interference for Heparin (50 mg/dL), Na-citrate (1000 mg/dL), Triglyceride (2500 mg/dL), EDTA (5 mg/dL) and Haemoglobin (1000 mg/dL). Bilirubin (> 15 mg/dL) and Turbidity (> 0.63 %) interfere with the test.

Limitations:	None
Comparison with Nephelometry:	$y = 1.0096x - 0.2344 / r = 0.9978$
Stability at 4°C:	at least 3 years after production

BIBLIOGRAPHY

- Mount, J.N., J. Clin. Pathology, 22, 12 (1986)
- Schmidtz, A., et al., Diabetic Medicine, 5, 126 (1988)

-  Numero lotto / Lot numer
-  Consultare la metodica operativa / consult instructions for use
-  Per uso diagnostico in-vitro / For in-vitro diagnostic use
-  Prodotto da / manufactured by
-  Data di scadenza / expiry date
-  Temp. Di Conservazione / storage temperature

