DIAGNOSTICA PRODUCTS

Liquid Reagents – ready to use

Microalbumin 5+1

Diagnostic reagent for the quantitative in vitro determination of Microalbumin in human urine by turbidimetric assay.

Ref.No.	Kit Size	Content
DIA020040	60 ml	2x25 ml R1 + 1x10 ml R2
DIA020041	120 ml	4x25 ml R1 + 1x20 ml R2
DIA020042	6 x 25 ml	5x25 ml R1 + 1x25 ml R2

Additionally offered:

DIA040050	5 x 1 mL	**Microalbumin Calibrator 5 Levels**
DIA040100	1 x 1 mL	**Microalbumin Calibrator**
DIA030070	1 x 1 mL	**Microalbumin Control**

GENERAL INFORMATION

Method	Immunoturbidimetric
Reaction	Nonlinear, endpoint
Wavelength	340 nm
Assay Temperature	18 – 37 °C
Sample	Urine
Measuring Range	approx. 0 – 400 mg/L
Sensitivity	4 mg/L (Cobas Mira)
Hook Effect	> 6,000 mg/L

Automated Test Procedure

Instrument dependent – please ask for applications

REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION
Microalbumin Antibody Reagent	
Phosphate buffered saline	
Polyclonal goat anti-human Albumin antibody	variable
Sodium azide	0.095 %
Microalbumin Buffer	
Saline	9 g/L
Enhancer	
Sodium azide	0.095 %

REAGENT PREPARATION

The reagents are liquid and ready to use.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light. Close immediately after use.

Stability: at 2 – 8 °C up to the expiration date
at 18 – 25 °C 1 month

Do not freeze!

SAMPLE STABILITY AND STORAGE

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

Stability: at 2 – 8 °C 48 hours
at – 20 °C 3 months

Centrifuge the urine before assay. **Freeze only once!**

REFERENCE RANGE

0 – 25 mg/L (IFCC)

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

CALCULATION

Calculate and plot ΔA = (A2 – A1) of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and control(s) and read values in mg/L on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

INTERFERING SUBSTANCES

No interference up to:

Triglycerides	2500 mg/dL	**Hemoglobin**	500 mg/dL
Bilirubin	15 mg/dL	**Sodium Citrate**	1000 mg/dL
Heparin	100 mg/dL	**Turbidity**	2.5 %

MANUAL TEST PROCEDURE

Test Procedure without Sample Dilution:

Samples/Controls: ready to use

Calibration curve: Use Microalbumin Calibrator High to generate a calibration curve by making 1:2 serial dilutions of the calibrator with 0.9% saline as diluent or use the 5 level calibrator series. Use 0.9% saline as zero point.

Pipette into test tubes:	Calibrators	Samples/Controls
Buffer	1000 µL	1000 µL
Cal./Ctrls/Samples	24 µL	24 µL
Mix. Read A1 of calibrators and samples/controls at 340 nm. Then add:		
Antibody Reagent	200 µL	200 µL
Mix. Incubate 5 minutes at assay temperature. Read A2 of calibrators and samples/controls at 340 nm. Calculate: ΔA = (A2 – A1)		

TEST PRINCIPLE

The assay of Microalbumin is based on turbidimetric measurement. Turbidity is caused by the formation of antigen-antibody insoluble immuno complexes.

DIAGNOSTIC IMPLICATIONS

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.

PRECISION

Intra-Assay Precision

3 control solutions (low-medium-high) were consecutively measured 20x on the Hitachi 911 and the variation coefficient was calculated.

Expected Value	n	Mean	S.D.	C.V
Low	20	27.16	0.62	2.28
Medium	20	111.57	2.01	1.80
High	20	526.0	16.0	3.04

Inter-Assay Precision

3 control sera were measured daily on the Hitachi 911 analyzer after calibration.

Expected Value	n	Mean	S.D.	C.V
Low	20	22.29	0.65	2.93
Medium	20	90.69	0.60	0.66
High	20	192.27	1.03	0.53

METHOD COMPARISON

A comparison with Nephelometry gave the following results:
y = 1.1702 x + 1.4811; r = 0.9879

QUALITY CONTROL

All commercially available Control sera with Microalbumin values measured by this method may be used. We recommend the Diagnostica Microalbumin control.

CALIBRATION

The assay requires the use of Microalbumin Calibrators. We recommend the Diagnostica Microalbumin Calibrator 5 Level Series or the Microalbumin Calibrator.

AUTOMATION

Applications for automated systems are available upon request.

WARNINGS AND PRECAUTIONS

1. The Microalbumin reagents are intended for in vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.
3. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV antibodies, as well as for Hepatitis B surface antigen, using a method approved by the FDA

WASTE MANAGEMENT

Please refer to local requirements.

CE IVD 2°C 8°C

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