BIOLABO
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MANUFACTURER:
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MICROALBUMIN Turbidimetric Immunoassay

Reagent for quantitative determination
of the excretion of albumin (MAL) in the human urine

REF 23010	**R1** 1 x 50 mL	**R2** 1 x 5 mL	**R3**	1 x 1 mL
REF 23011	**R1** 2 x 50 mL	**R2** 1 x 10 mL	**R3**	1 x 1 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (manual or automated method).
I It allows the quantitative determination of the excretion of albumin (MAL) in the human urine to detect small secretions of albumin in the urines.

GENERALITIES (1) (2)

Diabetic nephropathy, which is accompanied by irreversible 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. Microalbumin. Therefore, detection of kidney (glomerular) damage that is minimal and reversible is important.

PRINCIPLE (1)

Photometric measurement of turbidity, corresponding to antigen-antibody reaction, by the end-point method at 340 nm.

REAGENTS

R1 **Microalbumin TIA** Buffer

NaCl 9 g/L
Accelerator
Sodium Azide 0.95 g/L

R2 **Microalbumin TIA** Anti-Albumin

Phosphate buffered Saline
Polyclonal Anti-Human Albumin (Goat) (variable)
Sodium Azide 0.95 g/L

R3 **MAL** Standard Super High

Pooled liquid stabilized human plasma (Sodium azide 0.95 g/L).

The concentration of this standard is batch-specific

(**Calibration value on the label of the vial**)

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Liquid Reagents, ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened,

- Reagents are stable until expiry date stated on the label.
- Do not freeze

I Once opened and free from contamination

- Reagents R1 and R2 are stable at least for 3 months at 2-8° C, 24 h at room temperature.
- Reagent R3 is stable at least for 6 weeks.

SPECIMEN COLLECTION AND HANDLING (1) (3)

24h Urines or 3 random urine samples collected over the course of 1 week (minimizes intraindividual variation).

If the test cannot be carried out on the same day, the urine may be stored at room temperature for 2 days and at 2-8°C for maximum 14 days.

It is recommended to use centrifuged urines.

LIMITS (7)

Tests measured on a clinical chemistry analyser COBAS MIRA:

Urea	Do not interfere up to 4300 mg/dL
Creatinine	Do not interfere up to 560 mg/dL
Calcium	Do not interfere up to 30 mmol/L
Uric acid	Do not interfere up to 31.8 mg/dL
Hemoglobin	Do not interfere up to 375 mg/dL
Bilirubin	Do not interfere up to 32.6 mg/dL
Turbidity	Do not interfere up to 0.280 abs
Glucose	Do not interfere up to 1000 mg/dL
Ascorbic acid	Do not interfere up to 25 mg/dL
Chlorides	Do not interfere up to 1400 mg/dL
Magnesium	Do not interfere up to 98 mg/dL

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIEL REQUIRED BUT NOT PROVIDED

1.Medical analysis laboratory equipment.
2.Spectrophotometer or Biochemistry Clinical Analyzer
3.Saline (NaCl 9g/L)

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

QUALITY CONTROL

- REF 23014: MAL Control
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

REFERENCE INTERVAL (4) (5) (6)

2nd morning urines (4):

Adults: < 20 mg Albumin /g Creatinine or
< 2,26 g (34,35 µmol) Albumin /mol Creatinine

Childs (3 to 5 years old) (5):
< 20 mg/L (0,304 µmol/L) Albumin or
< 37 mg Albumin /g Creatinine

24 h Urines (6):
< 20 mg/L (0,304 µmol/L)
< 30 mg/24h (0,456 µmol/24h)

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On a clinical chemistry analyser (COBAS MIRA).

Linearity range: between 2,2 mg/L and 200 mg/L

Above 400 mg/L, dilute the specimen with saline and re-assay considering the dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

Repeatability

Within run (n = 20)	*Low level*	*Normal level*	*High level*
Mean mg/L	22.3	48.6	98.1
S.D. mg/L	0.76	1.49	2.47
C.V. %	3.4	3.1	2.5

Reproducibility

Between run (n = 30)	*Low level*	*Normal level*	*High level*
Mean mg/L	23.5	48.5	100.3
S.D. mg/L	1.30	2.72	3.78
C.V. %	5.5	5.6	3.8

Sensibility: approx. 0.420 abs for 200 mg/L
approx. 0.080 for 20 mg/L

Specificity: Monospecific

Prozone effect: tested up to 6000 mg/L, no effect found within the measuring range (approx. up to 0.728 ΔA)

Comparison with a commercially available reagent (same method): using 100 specimens between 2.2 and 400 mg/L

y = 0.9961 x + 1.5992 r = 0.9974

Interferences: See § Limits

On-board stability (Cobas Mira):

2 separate reagents are stable 15 days

Calibration Frequency (Cobas Mira): 7 days

Make a new calibration when changing reagent batch, if quality control results are found out of the confidence interval and after maintenance operations

I CALIBRATION

- REF 23013 Standard Set Or
- Reagent R3 (Standard Super High): generate standard curve using successive 1:2 dilutions in saline up to 6 different levels including zero point).
- Use saline as zero point

Standards are traceable to Reference Material (RPPHS/CRM470) from IFCC

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

PROCEDURE

Let stand reagents, standards, control, assays at room temperature.

Before use, mix reagent R2 by gentle swirling.

Manual Procedure:

Realise standard curve (§ Calibration)

Pipette into well identified test tubes :	**Blank**	**Standards**	**Assays**
Buffer (R1)	900 µL	900 µL	900 µL
Saline	60 µL		
Standards		60 µL	
Specimen			60 µL
Mix well. Record absorbance A1 against blank at 340 nm			
Anti-MAL (R2)	150 µL	150 µL	150 µL
Mix well. Incubate for exactly 5 minutes at room temperature. Read absorbance A2 at 340 nm against Blank.			

1- With Manual Procedure on Spectrophotometer, performances and stability data should be validated by user

2- Applications proposal are available on request of other analysers

CALCULATION

Manual procedure:

Calculate ΔAbs (Abs A2 – Abs A1) for standards, controls and assays.
Plot a Standard Curve "Concentration = f(ΔAbs)".
Read the concentration of controls and samples on the graph.

Automatic Biochemistry analyser:

The analyser provides directly result.
For more details about calibration and calculation of results, refer to User's manual and specific application.

REFERENCES

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(4) *Hofmann W, Guder WG. A diagnostic program for quantitative analysis of proteinurea. J Clin Chem Clin Biochem 1989; 27:589-600.*

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(6) *Hasslacher CH. Akt Endokrin Stoffw 1989; 10:60-63.*

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