BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

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
Tel : (33) 03 23 25 15 50
Fax : (33) 03 23 256 256

CE

IVD **IN VITRO DIAGNOSTIC USE**

CLINICAL SIGNIFICANCE (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

Vial R1 **BUFFER** (Concentration in the Test)

Saline
Accelerator
Sodium Azide 0.95 g/L

Vial R2 **ANTI-MAL** (Concentration in the Test)

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

Vial R3 **MAL Standard Super High (REF 23012)**

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

The concentration of this standard is batch-specific

(see **Assigned value on the label of the vial**)

REAGENTS PREPARATION

Liquid Reagents, ready for use.

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country.

All specimens, standards and controls should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

STABILITY AND STORAGE

Store at 2-8° C, away from light (Do not freeze).

- Unopened reagents are stable until expiry date stated on the label.
- Once opened, when free from contamination, reagents R1 and R2 are stable at least for 3 months at 2-8° C, 24 h at room temperature and 30 days on the board of analyser.
- Once opened, when free from contamination:
  Well recapped and stored in the original vial, standard (vial R3) is stable at least for 6 weeks.

SPECIMEN COLLECTION AND PREPARATION (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.

INTERFERENCES (7)

Results of 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. Saline (0.9 %)
2. Standards and Controls.

CALIBRATION

- Vial R3 enclosed in the kit or Standard REF 23012
- Or Standard Set REF 23013 traceable to Reference Material (RPPHS/CRM470) from IFCC

Use as indicated in the insert (§ **MANUAL PROCEDURE**) to generate a reference curve.

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

It is recommended to calibrate in the following cases:
1. When changing batch of reagent.
2. After maintenance operations on the instrument.
3. If control values are out of range, even after using a new vial of serum.

QUALITY CONTROL

- BIOLABO Control REF 23014
- Assayed control referring to the same method.
- 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. Repeat the test with the same control.
2. If control is still out of range, use a new vial of control and repeat the test.
3. If control is still out of range, use a new vial of calibrator and repeat the test.
4. If control is still out of range, calibrate with a new vial of reagent.
5. If control is still out of range, please contact BIOLABO technical support or your local Agent.

EXPECTED VALUES (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

The performance studies for MAL reagents were realised on a clinical chemistry analyzer (COBAS MIRA).

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
Expected C.V. %	< 6%	< 4.5%	< 4.5%

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
Expected C.V. %	< 8%	< 6%	< 6%

Detection limit: approx. 2.2 mg/L

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

LINEARITY

The assay is linear between 2.2 and 400 mg/L.

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

MANUAL PROCEDURE

Let stand reagent and specimens at room temperature.

Standard curve:
Generate a Standard curve by successive 1:2 dilutions of Standard enclosed in the kit (vial R3) or Standard High REF 23012 in saline (5 different levels are recommended), or use the ready for use Standard Set REF 23013.
Use saline as sample to determinate zero point

Test:

Pipette into well identified test tubes :	**Blank**	**Standards**	**Assays**
Buffer (Vial R1)	900 µL	900 µL	900 µL
Saline	60 µL		
Standards		60 µL	
Specimen			60 µL
Mix well. Read absorbances (Abs A1) of standards, controls and assays at 340 nm against Blank.			
Anti-MAL (Vial R2)	150 µL	150 µL	150 µL
Mix well. Incubate for exactly 5 minutes at room temperature. Read absorbances (Abs A2) of standards, controls and assays at 340 nm against Blank.			

Note:
Application procedures on clinical chemistry analyzers are available upon request.

CALCULATION

Calculate the result as follows:

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.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.798, 800.*
(2) *Mount, J.N., J. Clin. Pathology, 22, 12 (1986)*
(3) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p*. 66-67 et *70-71*
(4) *Hofmann W, Guder WG. A diagnostic program for quantitative analysis of proteinurea. J Clin Chem Clin Biochem 1989;27:589-600.*
(5) *Hubbuch A. Results of a multicenter study of provisional reference ranges for albumin in urine of children and adults. Publication de Roche*
(6) *Hasslacher CH. Akt Endokrin Stoffw 1989;10:60-63.*
(7) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-21 to 3-22*

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | sufficient for | → dilute with