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

MICROALBUMIN Control

For Quality control of quantitative determination
of albumin excretion in human urine (MAL) by Turbidimetric Immunoassay

REF 23014 **R1** 1 x 1 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision : www.biolabo.fr

CE

IVD

Made in France

I: corresponds to significant modifications

INTENTED USE

Titrated control for the quality control during the determination of albumin excretion (MAL) in human urine by Turbidimetric Immunoassay.
I Suitable for manual procedure or automated instruments with BIOLABO reagents: REF 23010, REF 23011

REAGENTS

R1 MAL Control

Human origin

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

SAFETY CAUTIONS (1) (2)

BIOLABO reagents are designated for professional use in laboratory.
- Material Safety Data Sheet is available upon request.
- Each donor unit used to manufacture this product was tested and found non-reactive for HbsAg, antibody to Hepatitis C and antibody to HIV-1/HIV-2.
- However, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
- Waste disposal: 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

Ready for use

MATERIAL REQUIRED BUT NOT PROVIDED

1.BIOLABO Reagents (§ Intended Use)
2.REF 23013: MAL Standard Set

QUALITY CONTROL

Verify the integrity of the vial and batch-specific value before use
Run in accordance with the IFU of the reagent used.

STABILITY AND STORAGE

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

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- Transfer requested quantity, well recap vials and store at 2-8°C.
- Well recapped in the original vial, at least for 6 weeks when free from contamination.

Do not freeze

PROCEDURE

Run in accordance with the IFU of the reagent used

VALUES AND CONFIDENCE ITNTERVAL (3)

- The value is traceable to Reference Material (RPPHS/CRM470) from IFCC.
- **Batch-specific value** is indicated on the label of the vial

It is recommended that each laboratory validate each new batch-specific value before use.
For an optimal use, laboratories should establish their own values and confidence interval. These values must be periodically retested.

LIMITATIONS

Factors which may influence results are bacterial contamination, accuracy of reconstitution volume, respect of automated instrument procedure, temperature...

REFERENCES

(1) *Occupational Safety and Health Standards; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) ; 6, p.267-280*
(2) *Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990, p.1-12*
(3) TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.520

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