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	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

PRINCIPLE AND INTENTED USE

Accuracy control during the determination of albumin excretion (MAL) in human urine by turbidimetry or nephelometry.
BIOLABO MAL Control is suitable for manual procedure or automated instruments.

REAGENTS

Vial R1 **MAL Control**

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

The concentration of this control is batch-specific
(see § **ASSIGNED VALUES**).

SAFETY CAUTIONS (1) (2)

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

- Each individual donation intended for use in manufacture of protein standard serum was tested negative for hepatitis B suMALace antigen (HBsAg), anti-hepatitis C (anti-HCV) and anti-HIV 1 and HIV 2 by FDA approved test.
- However absence of infectious agents can never be proven, this plasma and all specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In the event of exposure the directive of the responsible health authorities should be followed.
- 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.

REAGENTS PREPARATION

Ready for use

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Reagents and standards:

REF 23010, REF 23011	MICROALBUMIN Reagents
REF 23012	MICROALBUMIN Super High Standard
REF 23013	MICROALBUMIN Standards Set

STABILITY AND STORAGE

Store at 2 - 8° C, away from light in well capped original vial.
Do not freeze

- Unopened, MAL Control (vial R1) is stable until expiry date stated on the label.
- Once opened, MAL Control is stable at least for 6 weeks when free from contamination.

INTERFERENCES

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

CALIBRATION

Refer to technical sheet of the reagent in use.

QUALITY CONTROL

It is recommended to :
✓Participate to external quality control program.
✓Control as indicated in technical sheet of the reagent.
✓Validate target values and ranges when using other reagents that BIOLABO reagents.

PROCEDURE

This Control should be used with BIOLABO reagents REF 23010, REF 23011 or kits referring to the same method in accordance with technical data sheet of the reagent in use. BIOLABO MAL Control has to be handled as patient serum.

ASSIGNED VALUES (3)

Make sure that the batch number stated on the label of the vial corresponds to the batch number indicated below.

	Albumin (mg/L)
LOT XXXXX	xxx (xxx-xxx)

Value of MAL Control is traceable to reference material (RPPHS/CRM470) from IFCC.
It is recommended that each laboratory validate each new batch-specific value before use. For an optimal use, laboratories should establish their own targets and ranges. These target values have to be periodically retested.

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. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.520

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