BIOLABO
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MANUFACTURER:
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MICROALBUMIN Standard Super High

For calibration of quantitative determination of the excretion of albumin (MAL) in the human urine by Turbidimetric Immunoassay

REF 23012	1 x 1 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD IN VITRO DIAGNOSTIC

PRINCIPLE AND INTENTED USE

Standard to dilute for the preparation of reference curve for quantitative immunochemical determination of the excretion of albumin (MAL) in the human urine.
Suitable for manual procedure or automated instruments.

REAGENTS

Vial R3 **MAL Standard Super High**

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

The concentration of this standard 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 surface 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 controls

REF 23010 REF 23011	MICROALBUMIN Reagents
REF 23014	MICROALBUMIN Control

INTERFERENCES

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

STABILITY AND STORAGE

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

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

PROCEDURE

This Standard 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. This Standard has to be handled as patient serum.

QUALITY CONTROL

BIOLABO MAL Control REF 23014
Or other assayed control plasmas referring to the same method.
It is recommended to :
✓Participate to external quality control program.
✓Control as indicated in technical sheet of the reagent.
✓Validate Calibration values when using other reagents that BIOLABO reagents.

ASSIGNED VALUES (3)

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

LOT xxxxx	Albumin (mg/L)
MAL Standard Super High	**xxx**

Value of MAL Standard is traceable to Reference Material (RPPHS/CRM470) from IFCC.

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