MICROALBUMIN CALIBRATOR SERIES (mALB CAL)

INTENDED USE

Microalbumin Calibrators are diagnostic products used to calibrate the Microalbumin Assay.

This product has been developed to guarantee precise results for the analytical range for various analysers.

CHARACTERISTICS

The calibration material is derived from normal serum obtained from volunteer donors. All donor serum has been found negative for Hepatitis B surface antigen and Anti-HIV antibody.

Calibration of Microalbumin Calibrators has been performed at Randox by immunoturbidimetry, with reference to material standardised against an appropriate International Reference Preparation. The assigned values for lots are listed below.

ASSIGNED VALUES

LOT NO.	Albumin (mg/l)	Albumin (mg/dl)	EXPIRY DATE
1980IT	0.0	0.00	2022-03-28
998MA	8.9	0.89	2022-03-28
999MA	18.3	1.83	2022-03-28
1000MA	47.5	4.75	2022-03-28
1001MA	101.5	10.15	2022-03-28
1002MA	203.5	20.35	2022-03-28

STABILITY AND PREPARATION

The Microalbumin Calibrators are supplied ready for use, and are stable up to the expiry date when capped and stored at +2°C to +8°C in the absence of contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

These solutions contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg) and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Material Safety Data Sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

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