

✓ **REFERENCE**



Microalbumin medium control	MACON-002 MACON-005	1 x 2 ml 1 x 5 ml	2-8 °C
Human origin albumin in synthetic urine biological fluid standardised with reference to ERM-DA470k/IFCC preparation, sodium azide (<1g / l)			
Batch number :	22B16		
Expiry date :	01/2023		
Control date :	16/02/22		
Control report number :	DGM-QAC-REP-22037		
Document prepared and signed by :	L.Ginneberge		

ingestion and contact with skin and mucous membranes. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

✓ **ANALYTICAL PERFORMANCES**

See the corresponding reagents technical sheet.

✓ **PREPARATION AND REAGENTS STABILITY**

The control is ready for use; once opened, they are stable until the expiry date provided they are kept at the marked temperature in a closed bottle to avoid any contamination.

✓ **METHOD OF ANALYSIS AND CALCULATION**

See the corresponding reagents technical sheet.

✓ **QUALITY CONTROL**

Accuracy and reproducibility : Analytical performance can be verified using the internal control serum in labs or with the Liquicheck Urine Chemistry TM (BIORAD) control sera (see dosages obtained with DiAgam reagents and stated on the sheet accompanying these controls).

✓ **BIBLIOGRAPHY**

- (1) Horton, J.K et al. Clin. Chim. Acta 186 (1989) 45.
- (2) Neumann, R.G; & Cohen, M.P. Clin. Chim. Acta 179 (1989) 229.
- (3) Mac Neil, M.L.W. et al. Clin. Chim. 37 (1991) 2120.
- (4) Giampetro, O. et al. Acta Diabetol. 28 (1992) 239.

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

Microalbumin control is synthetic biological urine fluids containing human-derived human albumin in known concentrations and diluted in HEPES pH 7.4 buffer containing stabilisers and sodium azide at <1g/l as a preservative.

✓ **PRINCIPLE OF TEST**

The microalbumin contained in the sample to assay reacts specifically with anti-human microalbumin antiserum and the turbidity induced by the formation of the antigen-antibody immune complex is measured at 340 nm. The measured turbidity is proportional to the microalbumin concentration contained in the sample.

✓ **PRECAUTIONS**

For in vitro single diagnostic use. To be handled by entitled Personnel. Products from human source were tested and found free from HBsAg and antibodies to HCV and HIV but this material should be treated just as carefully as potentially infective. Products containing sodium azide have to be handled with care ; avoid









MACON 22B16 IFU EN v07 17/02/22


	CONTROL	
	mg/l	
	Target	Range
Microalbumin	50	40 - 60

Values assigned from the reference ERM-DA470k/IFCC.

Symbols

The following symbols may appear on the packaging and labelling :

LOT	<i>Batch code</i>	BUF	<i>Buffer</i>
	<i>Use by</i>	CAL	<i>Calibrator</i>
	<i>Manufacturer</i>	H	<i>High</i>
IVD	<i>In Vitro Diagnostics Medical Device</i>	M	<i>Medium</i>
	<i>Temperature limitation (store at)</i>	L	<i>Low</i>
REF	<i>Catalogue number</i>	4 LEV	<i>4 levels</i>
	<i>Consult instructions for use</i>	5 LEV	<i>5 levels</i>
REAG	<i>Reagent</i>	6 LEV	<i>6 levels</i>
KIT	<i>Kit</i>	CONTROL	<i>Control</i>
CONT	<i>Contents</i>		<i>This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro</i>
Ab	<i>Antibody or Antiserum</i>		<i>Track version changes</i>

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