

✓ **REFERENCE**



Microalbumin Low Control	MACOS-002 MACOS-005	1 x 2 ml 1 x 5 ml	2-8 °C
Human albumin in synthetic urine standardised the reference ERM-DA470k/IFCC, sodium azide (< 1g/l)			
Batch number :	21K18		
Expiry date :	04/2023		
Control date :	02/12/21		
Control report number :	DGM-QAC-REP-21282		
Document prepared and signed by :	Do Bach Mai		

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, it is stable until expiry date if stored stoppered in appropriate temperature conditions and without any contamination (avoid pipetting and decantation).

✓ **METHOD OF ANALYSIS AND CALCULATION**

See the corresponding reagents technical sheet.

✓ **QUALITY CONTROL**

Accuracy and reproducibility: analytical performances can be checked with the internal quality control serum of the laboratory or with the Liphochek™ (BIO-RAD) Control urines (see the values range obtained with DIAGAM reagents and indicated on the accompanying BIO-RAD sheet).

✓ **BIBLIOGRAPHY**

Horton, J.K et al. Clin. Chim. Acta 186 (1989) 45.
Neumann, R.G; & Cohen, M.P. Clin. Chim. Acta 179 (1989) 229.
Mac Neil, M.L.W. et al. Clin. Chim. 37 (1991) 2120.
Giampetro, O. et al. Acta Diabetol. 28 (1992) 239.
Johnson, A.M.: A new international preparation for proteins in human serum, Arch. Pathol. Lab. Med. 117 (1993) 29-31.

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

The microalbumin control is a synthetic urine containing human albumin at fixed value diluted in HEPES pH 7.4 buffer containing stabilisers and sodium azide (<1g/l) as preservative.

✓ **PRINCIPLE OF TEST**

The human albumin reacts upon a specific antibody for human albumin and the turbidity induced by the formation of immune complexes is recorded at 340 nm. The turbidity measured is directly proportional to the albumin concentration of the control which can be used for the validation of the calibration curve and the stability during time of this curve in immunoturbidimetry.

✓ **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 ingestion and contact with skin and mucous membranes. Sodium azide









MACOS 21K18 IFU EN v04 04/03/22


	CONTROL	
	mg/l	
	Target	Range
Microalbumin	25	20 - 30

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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