High control microalbumin

✓ ***REFERENCE***

High control microalbumin	**MACOX-002 MACOX-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 :		**21K19**	
Expiry date :		**04/2023**	
Control date :		**02/12/21**	
Control report number :		DGM-QAC-REP-**21283**	
Document prepared and signed by :		**Do Bach Mai**	

✓ ***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 human albumin contained in the control reacts specifically with a corresponding anti-serum and the turbidity caused by the formation of the antigen-antibody immune complex is measured at 340 nm. The measured turbidity is proportional to the antigen concentration contained in the control which can be used for the immuno-turbidimetric quantitative determination of the microalbumin.

✓ ***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 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 TM Chemistry Urine (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.

CE

MACOX 21K19 IFU EN v04 04/03/22

	CONTROL mg/l	
	Target	**Range**
Microalbumin	**100**	**80 - 120**

Values assigned from the reference ERM-DA470k/IFCC.

DiAgam Avenue Louis Lepoutre 70 - 1050 BRUSSELS Belgium mail@diagam.com **Tél: +32 (0) 68 55 14 82** **Fax: +32 (0) 68 56 89 40**
DISTRIBUTEUR: DiAgam France – 130 Boulevard de la Liberté- 59000 LILLE **Tél: +33 (0) 3 20 42 85 17** **Fax: +33 (0) 3 20 54 22 07**

Symbols

The following symbols may appear on the packaging and labelling :

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

	*DiAgam Belgium: Rue du Parc Industriel 40, 7822 Ghislenghien, Belgium*
DiAgam Headquarters	*Avenue Louis Lepoutre 70, 1050 Bruxelles, Belgique*
Distributed by	*DiAgam France: Boulevard de la Liberté 130, 59000 Lille, France*