

✓ **REFERENCE**



5 calibrators KIT	MAREK-000	5 x 1 ml	2-8 °C
Human albumin in synthetic urine standardised from the reference ERM-DA470k/IFCC, sodium azide (< 1g/l)			
Batch number :	22G08		
Expiry date :	06/2024		
Control date :	18/07/22		
Quality control report :	DGM-QAC-REP-22177		
Document prepared and signed by :	Do Bach Mai		

✓ **ANALYTICAL PERFORMANCES**

See the corresponding reagents technical sheet.

✓ **PREPARATION AND REAGENTS STABILITY**

The calibrators are ready for use; once opened, they are 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).

Calibration: calibration curve and stability of calibration curve can be validated with the Diagam calibration control (**MACON-002**, **MACOS-002** and **MACOX-002**).

In case of analytical performances modification, calibrate the method again and contact the manufacturer if modifications are subsisting.

✓ **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 calibrators are synthetic urines 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 calibrators which can be used for the quantitative determination of microalbumin 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 may react with lead or copper plumbing to form highly explosive metal azides.

























MAREK 22G08 IFU EN v04 01/08/22


	CAL 1		CAL 2		CAL 3		CAL 4		CAL 5	
	mg/l		mg/l		mg/l		mg/l		mg/l	
	certified val.	U*	certified val.	U*	certified val.	U*	certified val.	U*	certified val.	U*
Microalbumin	25	1,3	50	2,5	100	5,0	200	10,0	400	20,0

U*: The certified uncertainty is the half-width of the 95% confidence interval of the mean.
Values assigned from the reference ERM-DA470k/IFCC.

Symbols

The following symbols may appear on the packaging and labelling:

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

	<i>DiAgam Belgium: Rue du Parc Industriel 40, 7822 Ghislenghien, Belgium</i>
<i>DiAgam Headquarters</i>	<i>Avenue Louis Lepoutre 70, 1050 Bruxelles, Belgique</i>
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