Multiparametric Control

✓ ***REFERENCE***

Multiparametric Control	MPCON-002	1 x 2 ml	2-8 °C
Human multiparametric biological fluid standardized from the reference ERM-DA470k/IFCC, sodium azide (< 1g/l)			
Batch number :		**21C25**	
Expiry date :		**03/2023**	
Control date :		**12/04/2021**	
Control report number :		DGM-QAC-REP-**21071**	
Document prepared and signed by :		**L. Ginneberge**	

✓ ***SAMPLES AND REFERENCE VALUES***
See the corresponding reagents technical sheet.

✓ ***COMPOSITION***
The multiparametric control is a human biological fluid diluted in HEPES pH 7.4 buffer containing stabilizers, sodium azide (<1g/l) as preservative and the following human proteins:
albumin, alpha-1 antitrypsin, alpha-1 glycoprotein acid, alpha-2 macroglobulin, antithrombin III, complement C3, complement C4, ceruloplasmin, haptoglobin, IgA, IgG, IgM, prealbumin and transferrin.

✓ ***PRINCIPLE OF TEST***
The human proteins of control react upon a specific antibody for corresponding protein and the turbidity induced by the formation of immune complexes is recorded at appropriate wavelength. The turbidity measured is directly proportional to the antigen 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 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.

✓ ***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 LiquichekTM (BIORAD) Control sera (see the values range obtained with DiAgam reagents and indicated on the accompanying BIO-RAD sheet).

✓ ***BIBLIOGRAPHY***
(1) Certification of proteins in the human serum. Certified Referenced Material ERM®-DA470k/IFCC. I. Zegers et al. http://irmm.jrc.ec.europa.eu/
(2) S. Blirup-Jensen et al. protein standardization V: value transfer. A practical protocol for the assignment of serum protein values from a reference material to a target material. Clin Chem Lab Med (2008); 46(10): 1470- 1479.
(3) G. Merlini et al. Standardizing plasma protein measurements worldwide: a challenging enterprise. Clin Chem Lab Med (2010); 48(11): 1567-1575.

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MPCON 21C25 IFU EN v06 23/11/21

Proteins:	CONTROL	
	g/l	
	Target	Range
Albumin	46,38	37,10 – 55,66
Alpha1-Antitrypsin	1,46	1,17 – 1,75
Alpha1-Acid Glycoprotein	0,87	0,70 – 1,04
Alpha2-Macroglobulin	2,25	1,80 - 2,70
Antithrombin III*	0,34	0,27 – 0,41
Complement C3	1,58	1,26 – 1,90
Complement C4	0,31	0,25 – 0,37
Ceruloplasmin*	0,54	0,43 – 0,65
Haptoglobin	1,46	1,17 – 1,75
IgA	2,38	1,90 – 2,86
IgG	10,89	8,71 – 13,07
IgM	1,08	0,86 - 1,30
Prealbumin	0,25	0 20 – 0 30
Transferrin	3,12	2,50 – 3 74

Values assigned from the reference ERM-DA470k/IFCC.
**AT-III and Ceruloplasmin is referenced to external controlds.*

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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

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