

✓ **REFERENCE**

5 calibrators KIT	MPREK-000	5 x 1 ml	2-8°C
Human multiparametric biological fluid standardised from the reference ERM-DA470k/IFCC, sodium azide (< 1g/l)			
Lot #	19E23		
Expiry date	12/2020		
Control date	23/05/2019		
Quality control report #	DGM-QAC-REP-19082		
Document prepared and signed by	L. Ginneberge		

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

Multiparametric calibrators are human biological fluids diluted in HEPES pH 7.4 buffer containing stabilisers, 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 calibrators 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 calibrators which can be used for the quantitative determination of this antigen 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 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 Liquichek™ (BIO-RAD) Control sera (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 (MPCON-002, MPCOS-002 and MPCOX-002).

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

✓ **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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Proteins:	CAL 1		CAL 2		CAL 3		CAL 4		CAL 5	
	g/l		g/l		g/l		g/l		g/l	
	certified val.	U*	certified val.	U*	certified val.	U*	certified val.	U*	certified val.	U*
Albumin (Vitros® System)	6,50	0,325	13,00	0,650	26,00	1,300	52,00	2,600	103,90	5,195
Albumin (other Systems)	7,60	0,380	13,65	0,683	25,51	1,276	51,02	2,551	101,53	5,077
Alpha-1-Antitrypsin	0,20	0,010	0,42	0,021	0,89	0,045	1,80	0,090	3,67	0,184
Alpha-1-Acid Glycoprotein	0,13	0,007	0,25	0,013	0,51	0,026	1,03	0,052	2,06	0,103
Alpha-2-Macroglobulin	0,32	0,016	0,65	0,033	1,24	0,062	2,43	0,122	4,86	0,243
Antithrombin III*	0,038	0,002	0,076	0,004	0,175	0,009	0,362	0,018	0,724	0,036
Complement C3	0,24	0,012	0,47	0,024	0,94	0,047	1,88	0,094	3,77	0,189
Complement C4	0,043	0,002	0,085	0,004	0,170	0,009	0,340	0,017	0,680	0,034
Ceruloplasmin*	0,095	0,005	0,165	0,008	0,303	0,015	0,596	0,030	1,220	0,061
Haptoglobin	0,21	0,011	0,40	0,020	0,82	0,041	1,63	0,082	3,28	0,164
IgA	0,33	0,017	0,65	0,033	1,31	0,066	2,61	0,131	5,24	0,262
IgG	1,55	0,078	3,10	0,155	6,21	0,311	12,40	0,620	24,82	1,241
IgM	0,14	0,007	0,30	0,015	0,59	0,030	1,16	0,058	2,34	0,117
Prealbumin	0,033	0,002	0,065	0,003	0,150	0,008	0,322	0,016	0,682	0,034
Transferrin	0,40	0,020	0,79	0,040	1,58	0,079	3,16	0,158	6,32	0,316

U* : The certified uncertainty is the half-width of the 95 % confidence interval of the mean.

Values assigned from the reference ERM-DA470k/IFCC.

*AT-III and Ceruloplasmin is referenced to external controls.