

✓ 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)			
Batch number :	21D27		
Expiry date :	09/2022		
Control date :	27/04/21		
Quality control report :	DGM-QAC-REP-21088		
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.

✓ 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™ (BIORAD) 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.



MPREK 21D27 IFU EN v08 23/11/21

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	6.66	0.333	12.34	0.617	23.32	1.166	46.64	2.332	93.94	4.697
Alpha-1-Antitrypsin	0.18	0.009	0.37	0.019	0.73	0.037	1.49	0.075	2.93	0.147
Alpha-1-Acide Glycoprotein	0.12	0.006	0.23	0.012	0.45	0.023	0.91	0.046	1.81	0.091
Alpha-2-Macroglobulin	0.32	0.016	0.63	0.032	1.26	0.063	2.25	0.113	4.50	0.225
Antithrombin III *	0.042	0.002	0.084	0.004	0.163	0.008	0.336	0.017	0.677	0.034
Complement C3	0.21	0.011	0.43	0.022	0.84	0.042	1.70	0.085	3.43	0.172
Complement C4	0.041	0.002	0.082	0.004	0.163	0.008	0.327	0.016	0.658	0.033
Ceruloplasmin *	0.082	0.004	0.141	0.007	0.262	0.013	0.529	0.026	1.004	0.050
Haptoglobin	0.19	0.010	0.38	0.019	0.76	0.038	1.53	0.077	3.09	0.155
IgA	0.30	0.015	0.62	0.031	1.23	0.062	2.47	0.124	4.97	0.249
IgG	1.47	0.074	2.94	0.147	5.87	0.294	11.77	0.589	23.71	1.186
IgM	0.14	0.007	0.28	0.014	0.55	0.028	1.10	0.055	2.22	0.111
Prealbumin	0.031	0.002	0.062	0.003	0.123	0.006	0.264	0.013	0.571	0.029
Transferrin	0.39	0.020	0.78	0.039	1.54	0.077	3.13	0.157	6.31	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.

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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