

✓ **REFERENCE**



5 calibrators KIT	IGREK-000	5 x 1 ml	2-8 °C
Human biological fluid standardised from the reference ERM-DA470k/IFCC, sodium azide (< 1g/l)			
Batch number :		21E13	
Expiry date :		05/2023	
Control date :		27/05/21	
Quality control report :		DGM-QAC-REP-21104	
Document prepared and signed by :		Ginneberge Linsley	

✓ **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 (IGCOS-002, IGCON-002 and IGCOX-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.



IGREK 21E13 IFU EN v03 27/05/21

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

IgG CSF 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: IgG.

✓ **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.























	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.	$U^*$
<b>IgG CSF</b>	<b>12.07</b>	<b>0.604</b>	<b>24.47</b>	<b>1.224</b>	<b>49.20</b>	<b>2.460</b>	<b>96.53</b>	<b>4.827</b>	<b>183.33</b>	<b>9.167</b>


$U^*$  : 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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