

✓ **REFERENCE**



5 calibrators KIT	CYREK-000	5 x 1 ml	2-8 °C
Human Cystatin C in synthetic biological fluid standardized from the international standard ERM-DA471/IFCC1, sodium azide (< 1g/l).			
Batch number :		22F10	
Expiry date :		05/2024	
Control date :		24/06/22	
Quality control report :		DGM-QAC-REP-22138	
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.

✓ **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.

Calibration: Calibration curve and stability of calibration curve can be validated with the DiAgam calibration controls (CYCOS-002, CYCON-002, CYCOX-002).

Calibrate when the quality control results are outside acceptable range (contact the manufacturer if the deviations subsist), when the reagent lot number changes or when government regulations require.

✓ **BIBLIOGRAPHY**

(1) I. Zegers et al. Certification report – Certification of cystatin C in the human serum reference material ERM®-DA471/IFCC

http://www.erm-crm.org/ERM_products/search/reports/DA471.pdf



CYREK 22F10 IFU EN v01 24/06/22

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

Cystatin C calibrators are synthetic biological fluids containing human Cystatin C at fixed value diluted in HEPES pH 7.4 buffer containing stabilizers and sodium azide (<1g/l) as preservative

✓ **PRINCIPLE OF TEST.**

The human serum sample reacts upon colloidal gold coated with a mixture of polyclonal antibodies to Cystatin C. In the presence of cystatin C, the particles agglutinate, inducing a red shift in the absorption spectrum of the colloid. This induces an increase of the optical density at 600 nm, which is directly proportional to the ferritin concentration in the sample.

✓ **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^*
Cystatin C	0.440	0.022	0.842	0.042	1.617	0.081	3.240	0.162	6.620	0.331


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

Values assigned from the reference ERM-DA471/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>
<i>Distributed by</i>	<i>DiAgam France: Boulevard de la Liberté 130, 59000 Lille, France</i>

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