

✓ **REFERENCE**

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/IFCC ¹ , sodium azide (< 1g/l)			
Lot #	19H09		
Expiry date	08/2021		
Control date	28/08/2019		
Quality control report #	DGM-QAC-REP-19120		
Document prepared and signed by	L. Ginneberge		

✓ **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.

✓ **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



CYREKFTEN 28/08/2019 v00

Cystatin C	ROCHE® SYSTEMS	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5
		mg/l	mg/l	mg/l	mg/l	mg/l
		0.466	0.866	1.677	3.493	6.810

Value assigned from the Cystatin C international standard ERM-DA471/IFCC.
 Please contact your supplier in case of other analyzers utilization.