

✓ **REFERENCE**

5 calibrators KIT	CPRSK-000	5 x 1 ml	2-8°C
Human CRP in synthetic biological fluid standardized from the reference ERM-DA474/IFCC, sodium azide (< 1g/l)			
Lot #	15110		
Expiry date	02/2017		
Control date	16/09/2015		
Quality control report #	DGM-QAC-REP-15099		
Document prepared and signed by	L.Ginneberge		

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

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

✓ **PRINCIPLE OF TEST**

The human CRP reacts upon a specific antibody for human CRP and the turbidity induced by the formation of immune complexes is recorded at 340 nm. The turbidity measured is directly proportional to the CRP concentration of the calibrators which can be used for the quantitative determination of CRP 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 (CPCON-002).

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

✓ **BIBLIOGRAPHY**

- (1) H. Emons et al. Certification report - The Certification of the Mass Concentration of C-reactive Protein in Human Serum - ERM[®]-DA474/IFCC (2011). http://www.erm-crm.org/ERM_products/search/reports/DA474.pdf
- (2) I. Zegers et al. Standardizing plasma protein measurements worldwide: a challenging enterprise. Clin. Chem. Lab. Med. (2010); 48:11: 1567-1575



CPRSKFTEN 15/09/2015 v03

CRP	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*
	2.90	0.2	6.14	0.3	12.02	0.6	48.74	2.4	200.00	10.0

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

Values assigned from the reference ERM-DA474/IFCC.