Protein C Reactive Control (CRP)

✓ ***REFERENCE***

CRP Control	CPCON-002 CPCON-005	1 x 2 ml 1 x 5 ml	2-8 °C
Human CRP in synthetic biological fluid standardized from the reference ERM-DA474/IFCC, sodium azide (< 1g/l)			
Batch number :		**21D23**	
Expiry date :		**10/2022**	
Control date :		**10/05/21**	
Control report number :		DGM-QAC-REP-**21085**	
Document prepared and signed by :		**L.Ginneberge**	

✓ ***SAMPLES AND REFERENCE VALUES***
See the corresponding reagents technical sheet.

✓ ***COMPOSITION***
The CRP control is a synthetic biological fluid containing human CRP at fixed value diluted in HEPES pH 7.4 buffer containing stabilisers 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 control which can be used for the validation of the calibration curve and the stability during time of this curve 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 control is ready for use; once opened, it is 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).

✓ ***BIBLIOGRAPHY***
(1) H. Emons et al. Certification report - The Certification of the Mass Concentration of C-reactive Protein in Human Serum - ERM®-DA474/IFCC
(2) I. Zegers et al. Standardizing plasma protein measurements worldwide: a challenging enterprise. Clin. Chem. Lab. Med. (2010); 48:11: 1567-1575

CE

CPCON 21D23 IFU EN v07 10/05/21

	CONTROL mg/l	
	Target	**Range**
Protein C Reactive (CRP)	**20**	**16 - 24**

Values assigned from the reference ERM-DA474k/IFCC.

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Symbols

The following symbols may appear on the packaging and labelling :

LOT	*Batch code*	BUF	*Buffer*
	*Use by*	CAL	*Calibrator*
	*Manufacturer*	H	*High*
IVD	*In Vitro Diagnostics Medical Device*	M	*Medium*
	*Temperature limitation (store at)*	L	*Low*
REF	*Catalogue number*	4 LEV	*4 levels*
	*Consult instructions for use*	5 LEV	*5 levels*
REAG	*Reagent*	6 LEV	*6 levels*
KIT	*Kit*	CONTROL	*Control*
CONT	*Contents*	CE	*This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro*
Ab	*Antibody or Antiserum*		
			Track version changes

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