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CRP

Package Size

REF	11241	1 x 10 ml	CRP Reagent Kit
	11141	4 x 100 ml	CRP Buffer Kit

IVD

Intended Use

Immunoturbidimetric test for the quantitative determination of C-reactive protein (CRP) in human serum and plasma. The CRP reagents in combination with CRP Standard is designed for manual and automated working techniques.

Clinical Significance

CRP is an acute phase protein which is synthesised in the liver. Inflammatory processes, bacterial infections, polytrauma, myocardial infarction and certain other diseases (e.g. M. Bechterew, M. Crohn, rheumatoid arthritis) are accompanied by a significant increase of the CRP concentration in serum. Following surgery, the CRP concentration will also be elevated. It has been shown that persistently increased CRP levels may indicate a bad prognosis for the patient's outcome. Therefore, monitoring of the CRP concentration can be helpful to initiate necessary treatment in time.

Method

Human CRP reacts with anti-human CRP antibodies in the presence of CRP buffer. The resulting immune complexes generate a turbidity of the reaction mixture which is proportional to the CRP concentration. Possible interference by lipemia is eliminated by lipid clearing factors (LCF).

Content

	11241	**11141**	
REF			
BUF	1 x 40 ml	4 x 100 ml	
AS	1 x 10 ml		
BUF	**CRP buffer (R1)**		
	Good's buffer (pH 7.5)		20 mmol/l
	Polyethylene glycol 6000		<5%
	Detergents		2%
	Sodium azide		0.95 g/l
AS	**CRP Antiserum (R2)**		
	Anti-human CRP antibody (goat)		20%
	Sodium azide		0.95 g/l

Reagent Preparation

BUF (R1) and AS (R2) are ready for use.

Reagent Stability

BUF (R1) and AS (R2) are stable up to the stated expiry date if stored at 2...8°C. Once opened, the reagents are stable for 60 days if closed properly and stored at 2...8°C.

Specimen

Serum, plasma (heparin, EDTA, NaF, citrate)

Specimen stability

Sample type	**20...25°C**	**2...8°C**	**-20°C**
Serum/plasma	11 days	2 months	3 years

Calibration

For calibration the CRP Standard should be employed according to the procedure shown in the CRP Standard package insert. The specific assigned calibration value stated on the CRP Standard label has to be used.

REF	STD	**Content**
11341	CRP Standard	2 x 1 ml

The CRP values in CRP Standard are traceable to the international reference material ERM-DA472/IFCC.

Assay

Wavelength: 340 nm
Optical path: 1 cm
Temperature: 37°C
Measurement: against H_2O

Pipetting Scheme

The pipetting scheme for HumaLyzer 4000 can be accessed via:
www.human.de/aps-cc

	RB	STD	Sample
Dist. Water	50 µl	–	–
STD		25 µl*	–
Sample	–	–	50 µl
BUF (R1)	1000 µl	1000 µl	1000 µl
	Mix gently and incubate for 5 minutes at 37°C. Measure absorbance of RB_1 and A_1 of sample / STD.		
AS (R2)	250 µl	250 µl	250 µl
	Mix gently and incubate for 5 minutes at 37°C. Measure absorbance of RB_2 and A_2 of sample / STD.		
	$\Delta A_{(sample\ /\ STD)} = (A_{2sample\ /\ STD} - A_{1sample\ /\ STD}) - (A_{RB2} - A_{RB1})$		

*STD volume halved or 50 µl, diluted 1:2 with physiological saline. Always use freshly prepared dilutions.

Calculation of the CRP concentration

for 1-point calibration

$$C_{sample}\ [mg/l;\ mg/dl] = 0.5 * C_{STD} * \frac{\Delta A_{sample}}{\Delta A_{STD}}$$

for multi-point calibration

On automated analyzers CRP concentrations are calculated by a calibration curve. The dilution scheme for the CRP Standard is included in the CRP Standard leaflet.

Automation

Proposals to apply the reagents on analysers are available on request. Each laboratory has to validate the application in its own responsibility.

Quality Control

For quality control use following recommended control material or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

REF	CONTROL	**Content**	**Level**
13010	TURBIDOS	4 x 3 ml	2 levels

Reference ranges

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

Age	**[mg/l]**	**[mg/dl]**
Newborns to 21 days	up to 4.1	up to 0.41
Children 2 months to 15 years	up to 2.8	up to 0.28
Adults	up to 5.0	up to 0.5

Performance Characteristics

Linearity: The concentration ranges for linearity are:	
1-point calibration	up to 250* mg/l
multi-point calibration	up to 150** mg/l
*when BUF kit, REF 11141 is used: up to 200 mg/l **depends on LOT specific CRP Standard concentration Samples with concentrations above the linearity range should be diluted with physiological saline (1:3) and re-run. The result has to be multiplied with the dilution factor.	
Interferences: Interfering substances were added to a known sample. No interference was detected up to following concentrations:	
Bilirubin	up to 40 mg/dl
Hemoglobin	up to 500 mg/dl
Triglycerides	up to 2500 mg/dl
Prozone Effect: No prozone effect was detected up to following concentration:	
	up to 2000 mg/l

Typical performance data can be found in the Verification Report, accessible via:
www.human.de/data/gb/vr/tu-crp.pdf or
www.human-de.com/data/gb/vr/tu-crp.pdf
If the performance data are not accessible via internet, they can be obtained free of charge from your local distributor.

Notes

1. Never add new reagents (BUF, AS) to existing bottles.
2. Recalibration is required when new LOTs of BUF or AS are used.
3. Precipitates in the reagents or values of control sera outside the allowed range may be indications for reagent's instability. Such reagents should not be used.

Safety Notes

BUF Warning

H319 Causes serious eye irritation.
P234 Keep only in original container.
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P281 Use personal protective equipment as required.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.
P401 Store in accordance with local/regional/national/international regulations.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

References

1. Dowton S.B., Colton H.R., Acute phase reactants in inflammation and infection. Seminars in Hematology **25**, 84 (1988)
2. Peltola H.O., Valmari P., Serum C-reactive protein as detector of pretreated childhood bacterial meningitis. Neurology **35**, 251 (1985)
3. Schumann G., Dati F., Laboratoriumsmedizin **19**, 401 (1995)
4. Ledue T.B., Rifai N., Clin. Chem. **49**, 1258 (2003)
5. Young D.S., Effects of Drugs on Clinical Laboratory Tests, 5th ed, AACC Press (2000)
6. DGKL, Die Qualität diagnostischer Proben, 7th ed, Heidelberg (2012)

TU-CRP INF 1114101 GB 07-2020-021

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