CRP (C-Reactive Protein) (2-8°C)

(TURBIDIMETRY)

CATALOGUE NUMBER	KIT SIZE (ml)
MPRCRP1	1x40ml/1x10ml/1x1ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
CRP Turbidimetry is intended to be used for quantitative measurement of C-Reactive Protein in human serum and plasma.

Clinical Significance:
CRP is an acute phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/l in 12-24 hours.

Test Principle:
Latex particles coated with anti-human CRP become agglutinated when mixed with samples containing CRP. The agglutination causes an absorbance change proportional to the CRP concentration in the sample, that can be quantified by comparison with a calibrator of known CRP concentration.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
R1 – Buffer	Tris Buffer	20 mmol/l (pH 8.2)
	Preservative	
R2 – Latex Reagent	Latex particles coated with goat IgG anti-human CRP Preservative.	pH 7.3
CRP Calibrator	Human serum based CRP	Concentration stated on vial label. (CRM 470/RPPHS)

Precautions:
Components of human origin have been tested and found to be negative for the presence of HBsAg and antibody to HCV and HIV (1/2). Nevertheless, handle the reagents as potentially infectious.

Reagent Preparation and Stability:
Buffer R1: Liquid, ready to use.
Latex Reagent R2: Liquid, ready to use.
R1 and R2 are stable to the expiry date when stored unopened at 2 - 8°C. Once opened store tightly capped without contamination at 2 - 8°C. Do not use reagents after the expiry date.
Exercise the normal precautions associated with the handling of laboratory reagents and dispose of carefully according to local guidelines.
CRP Calibrator: Lyophilised. Reconstitute with 1ml of distilled water. Mix gently and stand at room temperature for 10 minutes before use. Stable for 1 month at 2 - 8°C or 3 months at -20°C.

Sample Collection, Preparation and Stability:
Collect serum and plasma by standard venepuncture technique. CRP is stable in serum and plasma up to 7 days at 2 - 8°C or 3 months at -20°C. Samples with presence of fibrin should be centrifuged before testing. Do not use highly lipaemic or haemolysed samples.

Assay Procedure:

WAVELENGTH	546nm (530 – 550 nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Distilled Water

R1 - Buffer	800 µl
R2 – Latex Reagent	200 µl
Calibrator / Sample	10 µl
Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.	

Calculation:
CRP Concentration (mg/l) = $\frac{\text{A2-A1 Sample}}{\text{A2-A1 Calibrator}}$ x Concentration of Calibrator

Performance Characteristics:
Linearity:
Up to 150 mg/l. Dilute samples with higher concentration 1/5 in NaCl (0.9%) and rerun the assay. The linearity limit depends on the sample reagent ratio and the analyser used. Linearity be higher with decreasing the sample volume and the sensitivity of the test will be decreased.

Detection Limit:
Sample concentrations less than 2 mg/l give non-reproducible results.

Prozone Limit:
No prozone effect was observed at 800 mg/l.

Precision:
The reagent has been tested over 20 days, using three different CRP concentrations in an EP5 based study.

	CV %		
	9.2 mg/l	16.8 mg/l	57.97 mg/l
Total	7.3%	6.9%	5.9%
Within day	2.8%	3.1%	2.9%
Between Run	6.1%	4.7%	3.9%
Between Day	3.0%	4.0%	3.4%

Accuracy:
Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 50 samples of different concentrations of CRP were assayed. The correlation was: 0.99
$y = 1.101x + 2.518$, $r = 0.99$
The results for the performance characteristics depend on the analyser used.

Interferences:
Bilirubin (20 mg/dl), lipaemia (10 g/l) and rheumatoid factor (300 IU/ml) do not interfere. Haemoglobin interferes above 5 g/l. Other substances may interfere.

Notes:
The result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Application for Automated systems:
For Applications on automated systems – contact technical department.

Quality Control and Calibration Material:
It is recommended that a laboratory uses reference controls to verify reagent performance. Results obtained should fall within the specified ranges. If results fall outside these ranges actions should be taken in line with the laboratory's internal quality procedures.

References:

1. Lars-Olof Hanson et al. Current Opinion in Infect Diseases 1997; 10; 196-201.
2. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139-144.
3. Yoshitsugy Hokama et al. Journal of Clinical Lab. Status 1987; 1: 15-27.
4. Kari Pulki et al. Scand J Clin Lab invest. 1986; 46: 606-607.
5. Werner Muller et al. Journal of Immunological Methods 1985; 80: 77-90.
6. Shogo Otsuji et al. Clin Chem 1982; 28/10: 2121-2124.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Prewss 1995.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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