CRP
(Turbilatex method)

CHEMCount

INTRODUCTION
C-Reactive Protein is a non-specific acute phase-reactive protein which appears in the blood during an inflammatory process. In patients with inflammatory diseases the concentration of CRP increases and decreases more quickly than the red cells sedimentation rate. CRP lacks diagnostic value when the patients illness is not defined, but it is very useful for following-up inflammatory diseases, as well as for the differential diagnosis in certain cases.

METHOD PRINCIPLE
The reagent consists of a suspension of latex particles of homogeneous size sensitized with anti-CRP, capable of aggregation in the presence of CRP. This aggregation process produces an increase in the size of the latex particles which in turn produces an increase in the absorbance of the system.

KIT CONTENTS

R1 - CRP Buffer	1 x 40 ml
R2 - CRP Latex	1 x 10 ml
R3 - CRP Calibrator	0.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 10 days on board the analyser at 2-8°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY
Assay can be performed with use of separate R1-CRP and R2-CRP reagents or with use of working reagent. For working reagent preparation mix gently 4 parts of R1-CRP with 1 part of R2-CRP. Avoid foaming.

Stability of working reagent : 4 days at 2-8°C

CONCENTRATIONS IN THE TEST
CRP Latex Reagent : Suspension of Latex particles sensitized with anti- human CRP, sodium azide 0.9 g/L

CRP Buffer Solution : Phosphate buffer 100 mM, pH 6.5, sodium azide 0.9 g/L

WARNINGS AND NOTES
1. The Kit is for in vitro diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed

ADDITIONAL EQUIPMENT
- Automatic analyzer or photometer able to read at 540 nm;
- Thermostat at 37ºC;
- General laboratory equipment;

SPECIMEN
Fresh sera or stored at 2 - 8ºC for no longer than 48 h. It is necessary to freeze the sample when the assay is to be carried out after that period of time. Discard contaminated or hemolyzed sera.

PLOTTING OF MULTIPOINT CURVE
The CRP is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial Dilution Step

Reagent	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE
These reagents may be used both for manual assay (Sample Start and Reagent Start method) and in several automatic analyzers. Applications for them are available on request.

Wavelength	546 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette:

Reagent	Calibrator(C)	Test (T)
Working Reagent	1000 µl	1000 µl
Bring up to the temperature od determination. Then add		
Calibrator	10 µl	-
Sample	-	10 µl

Mix well, after about 10 sec. (37°C) read the absorbance A1 of the test (T) and calibrator (C) against air or water. After exactly 120 secs. (for all temperature) read the absorbance A2 of the test (T) and calibrator ©. Calculate ΔA/min. (A2- A1) for the test and calibrator.

CALCULATION
CRP concentration = ΔA (T) / ΔA(C) x calibrator concentration

REFERENCE VALUES
upto 6 mg/L

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL
To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

PERFORMANCE CHARACTERISTICS
- **Sensitivity / Limit of Quantitation:** 2 mg/L
- **Linearity :** up to 150 mg/L. Samples that give higher concentration should be diluted in saline Nacl 0.9% (1+4) and the final result have to be multiplied by 5
- **Specificity / Interferences**

  No interference was observed by Bilirubin (171 umol/l), Hemoglobin (5g/L), Triiglycerides (2.28 mmol/L), RF (210 Iu/ml), other drugs and substances may interfer in the test.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Manack, J.R. and Richards, CB., J. Immunol. 20, 1019 (1971)
2. Ritchie, RF., J. Lab. Clin. Med. 70, 512 (1967)
3. Pepys MB. et al., Ann. NY Acad. Sci, 389, 459 (1982)

SYSTEM PARAMETERS

Method	Fixed Time (2-Point)
Wavelength	540 nm
Zero Setting Temperature	Distilled Water
Setting Incubation	37° C
Temperature Incubation	37° C
Time	----
Delay Time	10 secs
Read Time	120 secs
No. of Reading	2
Interval Time	----
Sample Volume	0.01 ml (10 µl)
Reagent Volume	1.0 ml (1000 µl)
Calibrator Concentration	Refer Calibratorvial
Units	mg/L
Factor	----
Reaction Slope	Increasing
Linearity	150 mg/L

IVD

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