

TURBICHEM CRP

(Turbilatex method)

| KIT NAME | KIT SIZE | CAT. NO |
|-----------------|-----------|------------|
| Turbichem - CRP | 1 x 50 ml | TCRP00050M |



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 | 1 vial |

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 2-10°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 37°C;
- General laboratory equipment;

SPECIMEN

Fresh sera or stored at 2 - 8°C 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 Turbichem 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

| | 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 Dilution | 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 of 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 $\Delta A/\text{min.}$ ($A2 - A1$) for the test and calibrator.

CALCULATION

CRP concentration = $\Delta A(T) / \Delta A(C) \times \text{calibrator concentration}$

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 µmol/l), Hemoglobin (5g/L), Triiglycerides (2.28 mmol/L), RF (210 lu/ml), other drugs and substances may interfere 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 | Distilled Water |
| Temperature Setting | 37° C |
| Incubation Temperature | 37° C |
| Incubation Time | ---- |
| Delay Time | 10 secs |
| Read Time | 120 secs |
| No. of Reading | 2 |
| Interval Time | ---- |
| Sample Volume | 0.01 ml (10 ul) |
| Reagent Volume | 1.0 ml (1000 ul) |
| Standard Concentration | Refer Stadard vial |
| Units | mg/L |
| Factor | ---- |
| Reaction Slope | Increasing |
| Linearity | 150 mg/L |



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