TURBICHEM hsCRP

(Turbilatex Method)

KIT NAME	KIT SIZE	CAT. NO
Turbichem- hsCRP	1 x 50 ml	ThsC01040M

GENUINE BIOSYSTEM

INTRODUCTION

C-reactive protein (CRP) is an acute-phase reactant that reflects low- grade systemic inflammation. In response to an inflammatory stimulus, a rise in CRP level up to 1000 fold may be detected within 6 hours. CRP is sensitive but the increase in CRP is non-specific, thus interpretation of CRP value should be complimented by complete clinical history. CRP measurements may also be performed for ealy detection of infection in pediatrics and risk assessment of coronary heart disease.

METHOD PRINCIPLE

The Kit utilizes latex-enhanced immuno turbidimetry to measure the CRP level in human serum. During the test, CRP in the sample binds with the specific anti-CRP antibody that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of CRP in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

KIT CONDENTS

R1 - hsCRP Buffer	1 x 40 ml
R2 - hsCRP Latex	1 x 10 ml
R3 - hsCRP 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-hsCRP and R2-hsCRP reagents or with use of working reagent. For working reagent preparation mix gently 4 parts of R1-hsCRP with 1 part of R2-hsCRP Avoid foaming.

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

CONCENTRATIONS IN THE TEST

R1 - Glycine buffer solution. Sodium azide < 0.1%

R2 - Latex suspension, anti-CRP antibodies, glycine buffer, sodium azide < 0.1%

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 570 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

PLOTTING OF MULTIPOINT CURVE

The Turbichem hsCRP 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 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	570 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)
R1 hsCRP Buffer	800 µl	800 µl
Caibrator	10 µl	-
Sample	-	10 µl
Bring upto the temperature of determination. Then add		
R2 hsCRP Latex	200 µl	200 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 300 secs. (for all temperature) read the absorbance A2 of the test (T) and calibrator (C). Calculate ΔA/min. (A2- A1) for the test and calibrator.

CALCULATION

$$\text{hsCRP concentration} = \frac{\Delta A\,(T)}{\Delta A\,(C)} \times \text{calibrator concentration}$$

REFERENCE VALUES

upto 3 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

- **Linearity**: 0.2 – 300 mg/L (R≥0.990)
- **Precision**: Within Run: CV≤4%; Run-to-Run: Cv≤6%
- **Interference:** no interference detected for: ascorbic acid (50 mg/dL), Bilirubin (30 mg/dL), triglycerides (1000 mg/dL), and hemoglobin (500 mg/dL).

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Osmond, A.P., et al, Proc. Natl. Acad. Sci. 74:739-743, 1977.
2. Pepys, M.B. Lancet. 1:653-657, 1981.
3. Liuzzo, G., et al, N ENG J Med, 331:417-424, 1994.
4. Rifai, N. High-sensitivity C-reactive protein: a novel and promising arker of coronary heart disease. Clin Chem 47: 403-11; 2001.
5. Burtis C, Ashwood, ER (ed). Tietz Textbook of clinical Chemistry, #rd ed. Philadelphia, PA; WB Saunders Co; 493;1999.
6. Wasunna A, et al. C-reactive protein and bacterial infection in preterm infacnts. Eur J Pediatr 1990; 149: 424-427 2000.

SYSTEM PARAMETERS

Method	Fixed Time (2-Point)
Wavelength	570 nm
Zero Setting	Distilled Water
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	----
Delay Time	10 secs
Read Time	300 secs
No. of Reading	2
Interval Time	----
Sample Volume	0.01 ml (10 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	Refer Calibrator vial
Units	mg/L
Factor	----
Reaction Slope	Increasing
Linearity	300 mg/L

IVD CE

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