CRP TURBI

Diagnostic reagent for determination of CRP Turbi (C-Reactive Protein Turbi) concentration.

Liquid. Dual Reagents (Ratio: R1/R2: 4/1). Store at +2°C /+8°C. For in Vitro Diagnostic Use(IVD). Do not freeze.

WL:570 nm Method:FixedTKinetic/Incr

	Standard Tube	Sample Tube
R1	500µL	500µL
R2	500µL	500µL
Standard	10µL	0
Sample	0	10µL

Mix well and don't incubate, aspirate immediately. After adding sample or standard please don't wait and aspirate to photometer within 5 seconds. Incubation will be started inside photometer.

First calibrate test, then go to sample test. Calibration stability:>1month, Test time is 135 seconds. (Incubation time: 15 seconds). Linearity:> 200 mg/L

INTENDED USE

This test is applied for the quantitative determination of C-Reactive Protein (CRP) in serum.

TEST SUMMARY AND PROCEDURE [1,2,3,4,5,6,7,8]

After tissue damage or inflammation, liver synthesized C-Reactive Protein is one of the most sensitive acute phase reactants.

CRP tests are used for the detection of systemic inflammatory processes, evaluation of antibiotic treatment of bacterial infections, detection of intrauterine infections with concomitant premature amniorexia, distinguishing between active and inactive forms of diseases that are also infectious, detection of the presence of post-operative complications such as infected wounds, thrombosis and pneumonia at an early stage and distinguishing between infection and bone marrow transplant rejection. Postoperative monitoring of patients' CRP levels can help the detection of unexpected complications (constantly high or increasing levels). Measuring the changes in CRP concentration provides useful diagnostic information about how acute and how serious a disease is. It also allows making decisions about the occurrence of the disease. A persistent high serum CRP concentration is a serious prognostic sign, often indicating the presence of an uncontrollable infection.

The level of CRP in plasma increases dramatically after atherosclerosis, stress, trauma, infection, inflammation, surgery, or neoplastic proliferation. The increase occurs within 24 to 48 hours and the level is 2000 times normal. All tissue-related damage is expected to increase, but the finding is nonspecific.

Serum C-reactive protein causes precipitation of latex particles coated with anti-human C-reactive protein. The precipitation of latex particles is directly proportional to the CRP concentration and can be measured turbidimetrically.

Clinical diagnosis should not be made only with the findings of test results; integration of the laboratory data should be used in clinical diagnosis as well.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 540 nm
Linearity : 120 mg/L

REAGENT COMPONENTS

Reagent 1:
Glycine buffer : ≤ 0.12 mol/L
Sodium azide : ≤ 0.99 mol/L
pH : 8.6

Reagent 2:
Suspension of latex particles coated with anti-human CRP antibodies:
Sodium azide : ≤ 0.99 g/L

REAGENT PREPARATION

Reagent are ready to use.

REAGENT STABILITY AND STORAGE

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum is collected according to the standard procedures.
CRP in serum is stable for:

15 days at +20/+25°C.

2 months at +2/+8°C.

3 years at -20°C.

Unit Conversion:

Mg/dL x 10 = mg/L

REFERENCE INTERVAL (NORMAL VALUES)

Serum : < 5.0 mg/dL

It I recommended that each laboratory establish its own normal range

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used.

We recommend:

Assayed Control Serum Normal

Assayed Control Serum Abnormal

The assay requires the use of a CRP Standard (Calibrator) Liquid High.

Any commercially available Standard or Calibrator suitable for this method may be used.

*Calibration Stability: It is strongly depending of application to auto analyzers and auto analyzers specification. Calibration stability is 15 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of detection is 1.0 mg/L
Limit of Quantitation (LoQ) [values are based on Coefficient of Variation Percentage (CV) %≤20]:[11] 1.9 mg/
High Linearity: The method is linear up to 500 U/L.
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.
Linearity may considerably vary depending on the instrument used

Precision Studies:[12]
Repeatability (Within Run) (Intra-Assay)

Mean Concentration	SD*	CV%	n
9.0 mg/L	0.10	1.10	20
19.0 mg/L	0.17	0.89	20

Reproducibility (Run to Run) (Intra-Assay)

Mean Concentration	SD*	CV%	n
8.5 mg/L	0.19	2.23	40
19.0 mg/L	0.27	1.42	40

*SD: Standard Derivation

Prozone Effect: No prozone effect has been observed up to 1000 mg/L value which is tested for CRP Turbi.

Method Comparison:[13],[14]
Correlation with a comparative method is: r= 0.9994
According to Passing-Bablok equation:
Slope: 0.945
Intercept: -0.84

Interference: [15, 16, 17,18]

No significant interference was observed for hemoglobin, conjugated bilirubin, lipemia, rheumatoid factors up to the interferent concentration given in the table.

Interfering Substances and Concentration	CRP Turbi Target (U/L)	N	%Observed Recovery
Hemoglobin 500 mg/dL	21.0	3	92.0
Bilirubin 60 mg/dL	18.0	3	102.0
Lipemia 3300 mg/dL	21.0	3	97.0

Non-hemolyzed and non-iceteric samples must be used.

The acceptable interference limit is set 10% below the highest interference concentration within ±10% recovery ofthe target.
Interferences may affect the results due to medication or endogenous substances

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

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