Automated Procedure

Cat. No. 30350	R1	1 x	20	ml
	R2	1 x	20	ml
Cat. No. 30351	R1	2 x	20	ml
	R2	2 x	20	ml

Principle

When a sample is mixed with the Buffer and Antibody solutions, CRP in the sample combines specifically with anti-human CRP antibodies to yield an insoluble aggregate that causes increased turbidity. The degree of turbidity can be measured optically and is proportional to the amount of CRP in the sample.

Concentrations in the test

Reagent R1 Buffer pH = 7.5	50	mmol/L
Reagent R2 Anti-human CRP	1.0	mg/ml

Stability of reagents

Reagent R1: Liquid, ready to use. **Reagent R2:** Liquid, ready to use. The reagent is stable up to expiry date given on the label when stored at $+ 2 \rightarrow + 8$ °C. **Don't freeze.**

Reagent deterioration

The presence of precipitates in the reagents or values of control sera outside the manufacturer's acceptable range may be an indication of reagent's instability.

Specimen collection and handling

- 1. Fresh non-hemolyzed serum is recommended.
- 2. Sodium fluoride and anticoagulants such as oxalate, EDTA, citrate and heparin do not influence the assay.
- 3. The sample can be stored for 1 week at 2 8 °C, and for 6 months at 20 °C.

Calibrator

CRP Calibrator Cat. No. 15055

Quality control

Rheumatoid control Level 1 Cat. No. 15241

Rheumatoid control Level 2 Cat. No. 15242

A quality control program is recommended for all clinical laboratories. The analysis of control sera in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. The values obtained for the controls should fall within the manufacturer's acceptable ranges. If values are to be established for unassayed control sera, the laboratory should assay each serum a sufficient number of times to generate a valid mean and acceptable range.

Procedure

The reagent is designed to be used an commercially available automated analyzers.

Refer to the operating manual for a description of Instrument operation and specifications.

C-reactive protein (CRP-HS) High Sensitivity

Quantitative turbid metric immunoassay

Liquid Reagents



Note: Applications on various instruments are available upon request.

Linearity

0.02 – 100 mg/L (calibration with 180 mg/L).

0.02 - 100 mg/L (multipoint calibration, depending an highest standard concentration).

If the result exceeds 230 mg/L, repeat the test using diluted sample (1+4) with sodium chloride solution (0.9 %) and multiply the result by 5. An antigen excess does not occur up to 400 mg/L.

Interference

No interferences can found in this assay.

Precautions

- Reagents contain sodium azide. Don't swallow. Avoid any contact with skin and mucous membranes. Sodium azide may react with copper or lead plumping to form explosive compounds. Drains should be well flushed with a large amount of water when dcarding the reagents.
- 2. Don't mix reagents from two different lots.
- 3. Don't use reagents past the expiration date stated on each reagent container label.
- 4. Don't use the preparations, test solutions, and reagents for any other purpose than described herein for CRP-HS.

Reference range

Adults	Up to 5 mg/L		
Neonates up to 3 days	Up to 10 mg/L		

Since expected values are affected by age, sex, diet, geographical location, and other factors, each laboratory should establish its own expected values for this procedure.

References

- Whicher, J. C-reactive protein (CRP) in: Clinical Laboratory Diagnostics: use and assessment of clinical laboratory results/ ed. by Lothar Thomas.-1 .ed.-Frankfurt/Main 1998, p.700 – 710.
- Proposed ranges Deutsche Gesellschaft f
 ür Laboratoriumsmedizin, March 24, 1995.
- 3. Based on CRM 470 standardisation.

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