CRP

Latex turbidimetry

Product information

24CRP01-UN	**Meditest CRP**	**4x24 mL 2x12 mL**
24CRP01-AU	**Meditest CRP**	**4x24 mL 2x12 mL**
24CRP01-AB	**Meditest CRP**	**4x24 mL 2x12 mL**
24CRP01-ER	**Meditest CRP**	**4x24 mL 2x12 mL**
24CRP01-AR	**Meditest CRP**	**4x24 mL 2x12 mL**

Purpose

In vitro assay for the determination of quantitative c-reactive protein in human serum and plasma.

Summary

C-Reactive Protein (CRP) is an acute-phase protein produced by the liver in response to inflammation, infection, and tissue damage. The increase in CRP concentrations occurs much earlier than with other acute-phase reactants, and this rapid response to trauma or infection is the hallmark of CRP. Furthermore, CRP levels quickly return to normal at the end of an acute attack, making CRP useful for both the detection of acute attacks and the monitoring of treatment.

Test principle

This CRP test is based on the agglutination reaction between the C-reactive protein in the sample and the anti-human CRP antibodies covalently bound to latex particles, resulting in an increase in light scattering that can be measured turbidimetrically at 500-600nm. The concentration of CRP in the sample is then determined by comparing it with the multi-point calibration curve.

Reagents - working solutions

R 1 Diluent	Tris buffer Sodium chloride Sodium azide	<20 mmol/L <150 mmol/L <0.95 g/L
R 2 Latex	Latex particles coated with specific rabbit anti-human CRP Sodium azide	<0.95 g/L

Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).

If there is any damage on the package, do not use it Read the user manual carefully before use, do not use the expired assay kit Do not mix different lot reagents.
All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.
Take the necessary protective measures to prevent users from becoming infected during operation.

Use of reagents

Ready to use.

Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contamination is avoided during their use.
Do not use reagents after the expiration date. Signs of reactive deterioration: Presence of particles and turbidity.

Sample collection and preparation

Fresh human serum. See the literature for stability data5. Avoid hemolyzed or contaminated samples. Lipemic samples and/or samples that become cloudy after the freeze-thaw cycle should be clarified by high-speed centrifugation (15 min at 15000 rpm) prior to testing.

Required Materials (not included in the kit)

1. Cat# 24CRP01-DC Meditest Diachem CRP Calibrator
2. Cat# 24PRO01-DQ Meditest Diacheck Protein Control L1
3. Cat# 24PRO01-DQ Meditest Diacheck Protein Control L2
4. General laboratory equipment
5. Distilled or deionized water

Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

1.Test Conditions:
Wavelength: . 540 nm
Cuvette: . . . . . 1 cm light path
Temperature: .
2.Set the appliance to zero with distilled water.
3.Place the pipettes in a cuvette.

R (mL)	0.8
Sample (µL)	20

4. Mix and read the absorbent immediately (A1) and after 2 minutes (A2) of the sample addition

Calculation

$$\frac{(A2\text{-}A1)\ \text{sample}}{(A2\text{-}A1)\ \text{standard}} \times \text{calibrator concentration} = \text{CRP mg/L}$$

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Expected values

<6 mg/L

It is recommended that each laboratory establish its own normal range. The reference range was validated using the CLSI EP28-A3c protocol.

Limitations

There should be no significant interference with hemoglobin, bilirubin or intralipid. Interference in high-value rheumatoid factor specimens should be avoided by treating them with equal volumes of 10mmol/L dithiothreitol solution for 30 minutes.

Performance characteristics

Measuring range 0.5-175 mg/L

Precision

	Intra-assay			Inter-assay		
	Mean (%)	%CV	N	Mean (%)	%CV	n
Low	15	0.7	20	15	3.9	20
High	45	1.4	20	45	5.7	20

Sensitivity: 1 mg/L = 4.2 ΔA/min

Accuracy: Results obtained using Meditest reagents (y) showed no systematic differences when compared to other commercial reagents (x). The results obtained using 50 samples are as follows:

Correlation coefficient $(r)^2$: 0.99

Regression equation y= 0.968x + 1.197

The results of the performance characteristics depend on the analyzer used.

References

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4. Todd E W. J Exp Med 1932; 55: 267 - 280.
5. Klein, GC. Applied Microbiology 1970; 19:60-61.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

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