CRP

TURBIDIMETRY

Intended use:
Immunoturbidimetric assay for the in vitro quantitative determination of CRP in human serum and plasma.

Summary:
C-reactive protein is the classic acute phase protein to inflammatory reactions. It is synthesized by the liver and consists of five identical polypeptide chains forming a five-membered ring of molar mass 120 000 daltons. CRP is the most sensitive of the acute phase reactants, and its concentration increases rapidly during inflammatory processes. Complexed CRP activates the complement system beginning with C1q. CRP then initiates opsonization and phagocytosis of invading cells, but its main function is to bind and detoxify endogenous toxic substances produced as a result of tissue damage.
CRP assays are used to detect systematic inflammatory processes (apart from certain types of inflammation such as SLE and colitis ulcerosa); to assess treatment of bacterial infections with antibiotics; to detect intrauterine infections with concomi- tant premature amniorrhexis; to differentiate between active and inactive forms of disease with concurrent infection, e.g. in patients suffering from SLE or Colitis ulcerosa; to therapeutically monitor rheumatic diseases and assess anti-inflam- matory therapy; to determine the presence of postoperative complications at an early stage, such as infected wounds, thrombosis and pneumonia; and to distin- guish between infection and bone marrow transplant rejection. A variety of methods, such as nephelometry and turbidimetry are available for the determination of CRP. This CRP assay is based on the principle of immunological agglutination.

Test principle:
Immunoturbidimetric assay
Anti-CRP antibodies react with antigen in the sample to form an ntigen/antibody complex. Following agglutination, this is measured turbidimetrically. Addition of PEG allows the reaction to progress rapidly to the end point,increases sensitivity, and reduces the risk of samples containing excess antigen producing false negative results.

Reagent concentration:
R1:

TRIS/HCl buffer pH 7.5	100mmol/l
Polyethylene glycol ether Preservative	1-5%

R2: Suspension of latex particles coated with anti-human CRP antibodies, sodium azide.

Preparation and stability:
R1: Readyforuse.
R2: Readyforuse.
Unopened kit components: Up to the expiration date at +2°C to + 8°C
On board stability: R1: 28 days
R2: 28 days

Specimen:
Collect serum using standard sampling tubes. Li-heparin or EDTA-Plasma Stability:
3 days at +20°C to +25°C
8 days at + 4°C to + 8°C
Centrifuge samples containing precipitate before performing theassay.

Limitations - interference:
Criterion: Recovery within ±10% of initial value.
Icterus: No significant interference up to a bilirubin concentration of 50 mg/dl. Hemolysis: No significant interference up to a haemoglobin concentration of 400 mg/dl. Lipemia (Intralipid): No significant interference up to a triglyceride concentration of 1500 mg/dl.
There is poor correlation between turbidity and triglycerides concentration. Rheumatoid factors up to 1200 IU/ml do not interfere. A high-dose hook-effect may occur at CRP concentrations >50 mg/dl.

Testing procedure:
Applications for automated systems are available on request.
Materials provided
Working solutions as described above Additional materials required
Calibrators and controls as indicated below
0.9% NaCl

Manual procedure:	
Wavelength:	540 nm
Temperature:	+37°C
Cuvette:	1 cm
Zero adjustment:	against reagent blank
	Sample/Calibrator
Sample/Calibrator	10 µl
R1:	800 µl
R2:	200 µl
Mix, and Read A1 after 10 sec. incubate 2 min. at +37°C. Than read absorbance A2	
Calculation:	
A = (A2 - A1) sample or calibrator The concentration of CRP in patient sera has to be calculated linear method For zero value is recommended to use saline solution (0.9%)	

Measuring /reportable range:
1 - 150 mg/L
Determine samples having higher concentrations via the rerun function. On instru- ments without rerun function, manually dilute samples with 0,9% NaCl solution or distilled/deionized water (e.g. 1 + 2). Multiply the result by the appropriate dilution factor (e.g. 3).

Expected values:
Standardized < 5 mg/L (<0.5 mg/dL)
Each laboratory should investigate the transferability of the expected values to its own patients' population and if necessary determine its own reference range. For diagnostic purposes the rheumatoid factor results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

Analytical sensitivity (lower detection limit)
Detection limit: 1 mg/L (0.01 mg/dl)
The lower detection limit represents the lowest measurable CRP-concentration that can be distinguished from zero. It is calculated as three standard deviations of 21 replicates of the lowest standard.

Imprecision:
Reproducibility within run was determined using controls in an internal protocol (n = 20).Thefollowingresultswere obtained:

	Within run		
Sample	Mean mg/l	SD mg/l	CV %
sample 1	18.65	0.47	2.55
sample 2	30.31	0.49	1.61
sample 3	102.07	0.96	0.94
	Between day		
Sample	Mean mg/l	SD mg/l	CV %
Sample 1	18.74	0.31	1.63
Sample 2	33.02	0.65	1.98
Sample 3	107.92	1.70	1.57

Method comparison:
A comparison of the BIOANALYTIC CRP (y) with a commercial obtainable assay (x) with 102 samples gave the following result:
y = 1.09 x - 1.09; r = 0.997

Quality Control:
Control Serum:

RHEUMATOID CONTROL LEVEL 1	5 x 1 ml	#B10846
RHEUMATOID CONTROL LEVEL 2	5 x 1 ml	#B10849

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

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Calibration:

Standardization: This CRP method was calibrated against an international standard defined for CRP.

S1: BIOANALYTIC CRP CAL. SET 5 x 1 ml #B11907

Calibration frequency:

It is suggested to use Calibrator products produced by Bioanaliytic. It is suggested to use supplementary calibrator (isotonic or pure water) to conduct 2-point calibration. The calibration curve is formed automatically. When lot number is changed or QC is invalid, calibration shall be conducted again. Recalibrate the assay every 30 days under ideal conditions,
or when the following occur:
Change in reagent lot or significant shift in control values;
Major preventative maintenance was performed on the analyser or a critical part was replaced(Halogen Lamp).

Literature:

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Order information (Cat No) :

CC375	CR375	B22115	B27115	B30115	B32117	B35116	B80116
CC376	BCRP500	B24115	B27116	B30116	B33115	B36115	B80117
OL375	BCRP250	B24116	B27117	B30117	B33116	B36116	B80118
OL376	BCRP125	B24117	B27118	B30118	B33117	B36117	
KL345	B21115	B25115	B28115	B31115	B33118	B37115	
KL376	B21116	B25116	B28116	B31116	B34115	B37116	
AB375	B21117	B25117	B28117	B32115	B34116	B37117	
AB376	B21118	B25118	B28118	B32116	B35115	B80115	

SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions

Manufacturer
Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti
Adress : İkitelli O.S.B Mutsan San.Sit. M4 Blok No:17-19 Başakşehir/İSTANBUL
Tel:+90(212) 549 33 88- Fax:+90 (212) 549 55 50
Web :www.diaclinica.com