CRP

C-REACTIVE PROTEIN

For discrete analyzers
Mehtod: Immunoturbidimetry

Product Code:	**1418-0520**	**4 x 5 ml (R1) + 4 x 2 ml (R2)**
	1418-0527	**4 x 20 ml (R1) + 4 x 8 ml (R2)**

Store at 2 – 8°C
For *in vitro* use

INTENDED USE

MEDICON CRP is a set of immunoturbidimetric reagents for the quantitative determination of CRP in human serum or plasma, with BECKMAN COULTER AU400/600/600-IVD/640/2700/5400 and other discrete analyzers. For *in vitro* diagnostic use only.

CLINICAL SIGNIFICANCE

Increased CRP concentrations in the serum are observed in cases of inflammation, tissue necrosis or wounds. In contrast to other acute phase proteins, like α1-antitrypsine and haptoglobuline, CRP is not significantly affected by non-steroid hormones of endogenous (pregnancy) or exogenous origin. It appears, however, that pharmaceutical treatment with steroid or non anti-inflammatory medicines may significantly reduce CRP levels. CRP levels in serum are increased more dramatically when compared to other acute phase proteins. Thus, CRP comprises one of the most useful proteins of that category for the clinical assessment of patients. Increase of CRP levels during an inflammation is observed even in the neonatal period, when it's very significant for the diagnosis of bacterial septicemia. CRP levels may also rise in viral infections or spirochaete. Therefore, in lack of wound, very high CRP levels may indicate bacterial or viral infection. In bacterial meningitis very high initial CRP levels may be prognostic of neurological complications. Consecutive measurements of CRP levels are exceptionally useful for patient monitoring during the anti-microbial treatment, as well as post-operatively when protein levels increase in bacterial infection. Measuring CRP levels is also useful during clinical assessment in rheumatoid arthritis, systemic lupus erythematosus, vascular syndrome, bowel inflammation and myocardial infarction.
No cases of CRP deficiency have been reported. Levels are lower for infants than adults. Direct immunoturbidimetry and nephelometry are not sensitive enough for the diagnosis of premature infants or infinitesimal increases in acute phase proteins of the newborn.

METHOD PRINCIPLE

The immunoturbidimetric method is applied. The addition of anti-CRP antibodies leads to the formation of insoluble antigen-antibody aggregates resulting to the creation of turbidity which is measured as the increase of CPR absorbance at 340 nm.

METHOD LIMITATIONS

Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests".
The reagent is designed for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory practices and techniques. Avoid inhalation and contact with eyes and skin.

REAGENT COMPOSITION

Reagent 1 (R1)
Polyethylene glycol in Tris buffer
Non reacting ingredients, preservatives
Reagent 2 (R2)
Sheep anti-human CRP protein antibodies
Non reacting ingredients, preservatives

WARNINGS - PRECAUTIONS

- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- The reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

REAGENT PREPARATION

Reagents R1 and R2 are liquid, and ready to use. Vials bear barcode for recognition by BECKMAN COULTER AU Series analyzers.

REAGENT DETERIORATION

The reagents should not be used:

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.

SHELF LIFE

Unopened, the reagents are stable at 2 – 8°C up to the expiry date stated on the label. After opening, R1 and R2 remain stable for 2 months when stored refrigerated on the analyzer.

SAMPLE

Fresh,non hemolysed, non lipemic serum or heparinized plasma. CRP concentration is stable for less than 3 days at 2 – 8°C, for 6 months at –20°C and indefinitely at –70°C.

CALIBRATION

MEDICON provides the MEDICON CRP Calibrator (1478-0522) or BECKMAN COULTER ODR 3021 Serum Protein Multi-Calibrator (MEDICON code: 4478-0754). Recalibrate the assay every 1 week, after major maintenance is performed on the analyzer or a critical part is replaced or a significant shift in control values occurs.

QUALITY CONTROL

MEDICON provides the following products for quality control: Immunology Control levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04) or BECKMAN COULTER ODC0014 ITA Control Serum 1, ODC0015 ITA Control Serum 2, ODC0016 ITA Control Serum 3 (MEDICON code: 4478-1190, 4478-1191, 4478-1192).
Control target values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for CRP should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

CRP calibrator
Quality control material
Automated biochemistry analyzer
Common laboratory equipment

REFERENCE INTERVALS

Up to 0.7 mg/dL (adults)
Each laboratory should determine its own expected values as dictated by good laboratory practice.

WASTE DISPOSAL

This product contains sodium azide (NaN3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity
The assay is linear up to 30 mg/dL. When values exceed this range samples should be diluted accordingly.
Prozone Tolerance
No hook effect is observed up to 200 mg/dL.
Sensitivity
The lowest detectable level of CRP is estimated at 0.13 mg/dL.
The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision

Level (mg/dL)	Within Run CV%	Between Run CV%
4.42	2.01	2.83
10.66	1.23	1.81

Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).
Interference

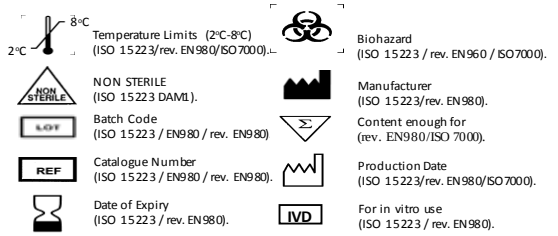
Lipemic:	insignificant up to 25 mg/dL Intrapalid®
Hemoglobin:	insignificant up to 125 mg/dL
Non Conj. Bilirubin:	insignificant up to 20 mg/dL
Conj. Bilirubin:	insignificant up to 20 mg/dL
Ascorbic acid:	insignificant up to 2.7 mg/dL

Refer to Young[4] for further information on interfering substances.
Method Comparison
A comparison was performed between this reagent and another commercially available product. The results were as follows on a BECKMAN COULTER AU series analyzer:
Y = 1.0736X + 0.4127 R=0.9970 N=87 Sample range: 0.6 – 18.97 mg/dL

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. The American Association for Clinical Chemistry, Inc. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Ohio, Hudson: Lexi-Comp Inc., 1997.

SYMBOLS



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MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

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