diatron

# CRP

**For use on Diatron Pictus® series analyzers**
**Method:** Immunoturbidimetry
**Product code:** 1419-0520, 1419-0522
**Package:** 6 x 10 ml (R1) + 6 x 2.5 ml (R2), 6 x 36 ml (R1) + 6 x 9 ml (R2)
**Store at:** 2° – 8°C
**For *in vitro* use only**

## INTENDED USE
Ready to use reagents for the quantitative measurement of CPR in human serum or plasma, specifically for use with Diatron Pictus® series 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 Haptoglobin, 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 medication may significantly reduce CRP levels. CRP levels in serum are increased more dramatically than other acute phase proteins. Thus, CRP comprises one of the most useful proteins of that category for clinical assessment of patients. Increase of CRP levels during inflammation is observed even in neonatal patients, when it's very significant for the diagnosis of bacterial septicemia. CRP levels may also rise in viral infections or spirochetes. Therefore, in lack of trauma, 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 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 an increase of test solution absorbance at 340/700 nm.

## METHOD LIMITATION
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 especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

## REAGENT COMPOSITION
**Reagent 1 (R1)**
Polyethylene glycol in Tris buffer.
Non reactive ingredients, preservatives.
**Reagent 2 (R2)**
Sheep anti-human CRP protein antibodies.
Non reactive 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 Diatron or MEDICON HELLAS (manufacturer) upon request.

## REAGENT PREPARATION
Reagents R1 and R2 are liquid, and ready to use when placed in the corresponding positions of the analyzer. The vials bear barcodes for automatic recognition by Pictus® 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 reagent is stable at 2°– 8°C up to the expiry date stated on the label. After opening, R1 and R2 remain stable for 28 days when stored in the cooled reagent tray of the Pictus® series analyzers.

## SAMPLE
Fresh, non-hemolyzed, non lipemic serum or heparinized plasma specimens must be used. 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
Diatron provides CRP Calibrator (1478-0522). Recalibrate the assay every 14 days for the Pictus® series analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

## QUALITY CONTROL
Diatron provides Immunology Control Levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04 respectively). Control recovery should lie within the acceptable range. Results outside the acceptable range 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 SUPPLIED WITH THE KIT
- CRP calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment

## REFERENCE INTERVALS
Up to 0.7 mg/dL (adults)
Expected values are based on current bibliography. Each laboratory should determine its own expected values as dictated by good laboratory practices.

## WASTE DISPOSAL
This product contains sodium azide ($NaN_3$), 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
The following values are representative of the reagent performance on Diatron Pictus® analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

| | Pictus® P400 | Pictus® P700/P500 |
|---|---|---|
| **Linearity** | Up to 30 mg/dL | Up to 30 mg/dL |
| **Hook effect** | > 170.0 mg/dL | > 170.0 mg/dL |
| **Lowest detection limit** | 0.24 mg/dL | 0.06 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** Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5A (20 consecutive days, 2 runs per day, 2 repeats per run)

| Pictus® P400 | | | Pictus® P700/P500 | | |
|---|---|---|---|---|---|
| Level (mg/dL) | Within Run CV% | Total CV% | Level (mg/dL) | Within Run CV% | Total CV% |
| 1.54 | 2.95 | 4.99 | 2.21 | 3.91 | 4.57 |
| 7.60 | 2.55 | 3.96 | 7.62 | 2.85 | 3.67 |

**Interferences:** Criterion recovery within ±20% from target value

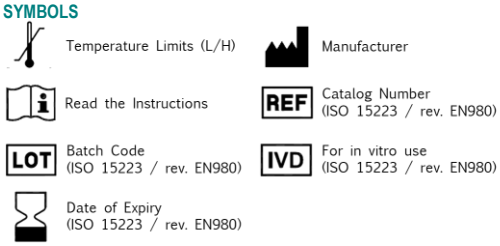
| | Pictus® P400 | Pictus® P700/P500 |
|---|---|---|
| Lipemia | Insignificant up to 200mg/dL Intralipid® | Insignificant up to 200mg/dL Intralipid® |
| Haemoglobin | Insignificant up to 500mg/dL | Insignificant up to 500mg/dL |
| Non conj. Bilirubin | Insignificant up to 20 mg/dL | Insignificant up to 20 mg/dL |
| Conj. Bilirubin | Insignificant up to 20 mg/dL | Insignificant up to 16 mg/dL |
| Ascorbate | Insignificant up to 3 mg/dL | Insignificant up to 3 mg/dL |

**Correlation:** A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

| | | | |
|---|---|---|---|
| **Pictus® P400** | | | |
| Y = 0.947X + 7.045 | R = 0.997 | N = 40 | Sample range: 0.48 – 18.3 mg/dL |
| **Pictus® P700/P500** | | | |
| Y = 0.916X + 6.39 | R = 0.997 | N = 43 | Sample range: 0.48 – 18.3 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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