CRP-LATEX

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

2°C – 8°C

REF 1419-0524 **Packaging:** 4 x 12 mL (R1) + 4 x 12 mL (R2)

Σ 400

INTENDED USE
Reagents for In Vitro quantitative automated measurement of the concentration of C-Reactive Protein – CRP in samples of human serum from the general patient population. Measurements of CRP are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid to the screening, evaluation, and management of acute and chronic inflammatory conditions.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

CLINICAL SIGNIFICANCE
CRP levels in serum rise faster and more dramatically than those of other acute phase proteins. CRP is therefore one of the most useful proteins in that category for the clinical evaluation of patients. 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 when compared to other acute phase proteins. Increase of CRP levels during 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 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.
Measurements within the reference intervals have been reported to have prognostic value in patients with acute coronary incidents, or in the prognosis of future coronary incidents.
CRP levels are lower in 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 new-born. Determination using this high sensitivity CRP-Latex reagent can help with timely diagnosis of infection in premature babies and infants, to address the requirement for pharmaceutical treatment and monitoring of its effectiveness. No cases of CRP deficiency have been reported.

METHOD PRINCIPLE
The turbidimetric method is applied. When the sample is mixed with buffer (Reagent 1) and antiserum solution containing anti-human CRP antibodies bound on latex particles (Reagent 2), CRP reacts selectively with anti-human CRP antibodies, resulting to the formation of insoluble complexes. The absorbance of the test solution at 590 nm is proportional to the concentration of CRP in the sample

METHOD LIMITATIONS
The reagent contains heterophilic antibody inhibitor, to eliminate non-specific binding that may interfere with the test. However, in the presence of excessive quantities of heterophilic antibodies, HAMAs or Rheumatoid factors, discrepant values of CRP may appear. This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent 1 (R1)	Reagent 2 (R2)
Tris buffer pH 7.4 Aggregation acceleration polymer. Non-reactive ingredients, preservatives	Anti-human CRP protein antibodies bound on latex particles. 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.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**
Reagents R1 and R2 are liquid, and ready to use when placed in the corresponding positions of the analyzer. Vials bear barcode for recognition by Diatron Pictus® P700 / P500 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 temperatures.

⚠ **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 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. CRP remains stable in serum for 7 days at 20 - 25°C and 2 months at 2 - 8°C. It has been reported that frozen specimens may give false-positive results.

CALIBRATION Diatron offers MEDICON CRP-Latex Calibrator (1478-0529) traceable to ERM-DA474. Calibrate the assay every 1 month. 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 offers MEDICON Immunology Control levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04). 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 Latex calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum: < 6 mg/L
Each laboratory should determine its own expected values as dictated by good laboratory practice.

⚠ **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® P700 or P500 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.
Linearity Up to 160 mg/L
Hook effect > 900.0 mg/L
Lowest detection limit 0.15 mg/L
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® P700 and P500	
Level (mg/L)	**%CV**
0.94	5.76
12.0	1.87
Level (mg/L)	**TOTAL %CV**
0.94	7.32
12.0	4.58

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbate	3 mg/dL

Refer to Young[4] for further information on interfering substances.

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer, and another, commercially available product. The results were as follows:
Y = 0.819X + 1.2321 R=0.986 N = 40 Sample Range: 0.06 – 156 mg/L

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

Manufacturer	IVD *In vitro* diagnostic medical device
Temperature Limit	REF Catalogue Number
Caution	Σ Contains sufficient for <n> tests

* PICTUS®: Registered Trademark of Diatron Medical Instruments Limited, Táblás utca 39, H-1097 Budapest, Hungary, used here after contractual agreement.

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