CRP LATEX CALIBRATOR

2°C 8°C

REF 1478-0529 **Packaging:** 5 x 1 mL

INTENDED USE

Material for the preparation of reference curves for the quantitative determination of C-Reactive Protein using Medicon CRP Latex reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro Diagnostic use only by trained laboratory professionals.

COMPOSITION

Liquid, non-hemolyzed, filtered human plasma and pleural fluid adjusted with stabilizers and preservative.

⚠ **WARNINGS – PRECAUTIONS**

- For in vitro use only
- The material contains sodium azide (NaN_3) <0.1%. Avoid swallowing and contact with skin and mucous membranes.
- Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1 and 2 using FDA approved methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents this product should be handled as a potentially infectious material.
- 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!

⚠ **PREPARATION**

Material ready to use. Swirl each vial gently before use to acquire homogenous mix. Avoid foaming. Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- CRP Latex reagent kit
- Automated biochemical analyzer
- Common laboratory equipment.

⚠ **STORAGE - STABILITY**

The unopened material remains stable at 2-8ºC until the expiry date stated on the label. Once opened the material remains stable for 1 month when stored tightly capped at 2-8ºC.

TEST PROCEDURE

A 6-point calibration curve should be used. Use saline (NaCl 0,9%) or deionized water as the zero calibrator. Consult the analyzer manual for the calibration procedure. After calibration, control values should fall within acceptable limits. If trends or sudden shifts are noticed, check all functional parameters.

Each laboratory should have guidelines for corrective actions in case of control values falling outside the acceptable limits.

Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

⚠ **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. Dispose of all waste material in accordance with local guidelines. Safety data sheet is available for professional use on request.

ASSIGNED VALUES – Lot specific

Please refer to the value sheet for the specific lot available at https://medicondoc.com

SYMBOLS

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