CRP CALIBRATOR

2°C 8°C

REF 1478-0522 **Packaging:** 5 x 1 mL

INTENDED USE

Material for the preparation of reference curves for the quantitative determination of C-Reactive Protein using Medicon 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 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.

⚠ **DETERIORATION**

The material should not be used:

- After prolonged exposure to direct sunlight or high temperature
- After the expiry date
- When microbial growth is evident

CALIBRATION PROCEDURE

6-point Calibration. For the first point use serum blank (saline) NaCl 0.9%.
Refer to the appropriate User's Guide and the accompanying Instrument Setting Sheet for analyzer-specific assay instructions for serum/plasma application.
If any trends or sudden shifts in values are detected, review all operating parameters. Control recovery should lie within acceptable intervals. Results outside the specified values even after recalibration could be due to reagent/calibrator/control deterioration, unsuitable storage conditions, instrument malfunction, or error during test procedure. Every laboratory should establish its own corrective measures in case control recovery lies outside acceptable intervals.
Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

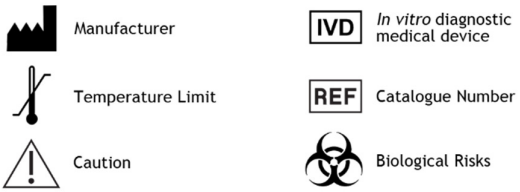
⚠ **WASTE DISPOSAL**

Dispose of all waste material in accordance with local guidelines for infectious or potentially infectious materials. 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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Version 2 - Last updated 2020.06.30

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