

REF 10799 6 x 1 mL BOTTLES, LEVEL 3

C-REACTIVE PROTEIN (CRP) QUALITY CONTROL LEVEL 3

Vials each containing 1 mL of stabilized, protein-based quality control material for C-reactive protein (CRP).

INTENDED USE

The EasyQC CRP materials are intended for use as a quality control material for the CRP turbidimetric assay, using the EasyRA CRP reagent and calibrator kit on the EasyRA® clinical chemistry analyzer.

For *in vitro* diagnostic use only. For professional use only.

INSTRUCTIONS FOR HANDLING, STORAGE AND STABILITY

The quality control material is stable until the expiration date on the label if stored unopened at 2 – 8°C. The QC material is stable for 3 months after opening when stored at 2 – 8°C.

SAFETY PRECAUTIONS AND WARNINGS

- 1 The human source material from which this product has been derived has been tested and found non-reactive for HBsAg, anti-HIV 1 / 2, anti-HCV and HIV-1 Ag. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled and disposed of as though they are capable of transmitting infectious diseases.
- 2 This material contains Sodium Azide as preservative. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with your eyes or if ingested, seek immediate medical attention. Refer to the Material Safety Data Sheet for risk, hazard and safety information.

INSTRUCTIONS FOR USE

- 1 Before opening the vial, allow the vial to warm to ambient temperature for 20 minutes.
- 2 Invert gently to assure homogeneity of the contents. Avoid foaming. Treat the control as you would a patient sample in accordance with the requirements of the test method.
- 3 The C-reactive protein controls are assayed using the same procedure as the patient test samples run in the test procedure. See package insert for the Medica CRP reagent.
- 4 Immediately recap the controls and return to 2 – 8°C when not in use.

QC Ranges

VALUE ASSIGNMENT

Values are assigned to each batch of CRP Control using a latex-enhanced immunoturbidimetric method, with reference to material standardized against an appropriate International Reference Preparation (CRM470).

The Table below contains the acceptable quality control ranges for CRP: Level 3

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Analyte:	Assigned Value	Units
EasyQC CRP Level 3	126.0 – 188.0	mg/L

Quality control results for this material may produce values that are higher than the upper limit of the linear range for the assay. When this occurs, the EasyRA Analyzer flags any result above 160 mg/L CRP as "LH" (Linear High). Quality control samples with results above 160 mg/L should be retested. If the "Re-run" icon is selected by the operator, the quality control sample will automatically be retested using one-third (1/3) the sample volume. The retest results are calculated to reflect the use of the smaller sample volume. This will extend the reportable range of the CRP test to 480 mg/L.

