

REF 10659 6 X 1 mL BOTTLES

C-REACTIVE PROTEIN (CRP) CALIBRATOR KIT

Vials each containing 1 mL of liquid-stable calibrator with different levels of CRP based on human source material. This multi-calibrator set was manufactured for Medica Corporation.

INTENDED USE

This CRP Calibrator Kit is intended to be used for the calibration of the Medica CRP assay on the EasyRA® Clinical Chemistry Analyzer when used in conjunction with the EasyRA CRP reagent. The CRP calibrators are used to establish points of reference that are used in the determination of values in the measurement of CRP in human serum and plasma. For *in vitro* diagnostic use. For professional use only.

SAFETY PRECAUTIONS AND WARNINGS

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.

INSTRUCTIONS FOR HANDLING, STORAGE AND STABILITY

The calibrators are stable until the expiration date on the label if stored unopened at 2 – 8°C. After the calibrators are opened, store the calibrator closed at 2 – 8°C. The opened calibrators are stable for 3 months at 2 – 8°C.

INSTRUCTIONS FOR USE

1. Before opening the calibrator vial, allow the vial to warm to ambient temperature for 20 minutes.
2. Mix by gentle swirling or inversion. **Do not shake.**
3. The C-reactive protein Multi-Calibrators are assayed using the same procedure as the patient test samples run in the test procedure. See package insert for the Medica C-reactive protein reagent.

VALUE ASSIGNMENT

Values are assigned to the CRP Calibrator Series using a latex-enhanced immunoturbidimetric method, with reference to material standardized against an appropriate International Reference Preparation (ERM-DA472).

The Table below contains the assigned values for the CRP Calibrator:
Please refer to the vial label for each lot for the exact calibrator values.

Lot No. 26091 Expires: 2027-02-28

Analyte:	Assigned Value
Calibrator Values for EasyRA	mg/L
EasyCal CRP Level 1	0.0
EasyCal CRP Level 2	2.5
EasyCal CRP Level 3	10.0
EasyCal CRP Level 4	20.0
EasyCal CRP Level 5	80.0
EasyCal CRP Level 6	160.0