

HIGH SENSITIVITY CRP CALIBRATOR SERIES (hsCRP CAL)

(HIGH SENSITIVITY CRP CALIBRANT)

CAT. NO. CP 2478
GTIN: 05055273201680
SIZE: 6 x 2 ml

INTENDED USE

This product is intended for *in vitro* diagnostic use in the calibration of CRP on clinical chemistry systems.

SAFETY PRECAUTIONS AND WARNINGS

The calibrator contains human CRP in a stabilised protein matrix. Human source material, from which the product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), Hepatitis C Virus (HCV) antibody, HBV DNA, HCV RNA and HIV DNA and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

For *in vitro* diagnostic use only, do not pipette by mouth, exercise the normal precautions required for handling laboratory reagents.

This material contains Sodium Azide. 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 eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Dispose of this material according to local regulations.

STORAGE AND STABILITY

Unopened: The hsCRP Calibrator Series is supplied ready for use and is stable up to the expiry date when capped and stored at +2°C to +8°C in the absence of contamination.

Opened: Once opened, the hsCRP Calibrator Series is stable for 30 days when stored at +2°C to +8°C in the absence of contamination. Only the required amount of product should be removed and the cap subsequently replaced. After use, any residual product should NOT BE RETURNED to the original vial.

MATERIALS PROVIDED

hsCRP Calibrators

| | | | |
|---------|------------|---------|------------|
| Level 1 | (1 x 2 ml) | Level 4 | (1 x 2 ml) |
| Level 2 | (1 x 2 ml) | Level 5 | (1 x 2 ml) |
| Level 3 | (1 x 2 ml) | Level 6 | (1 x 2 ml) |

MATERIALS REQUIRED BUT NOT PROVIDED

None

VALUE ASSIGNMENT

Calibration of hsCRP Calibrators has been performed at Randox by latex-enhanced immunoturbidimetry, with reference to material standardised against the European Reference Material ERM[®]-DA474/IFCC. The assigned values for the batch are listed below.

| LOT NO. | CRP (mg/l) | CRP (mg/dl) | EXPIRY DATE |
|---------|------------|-------------|-------------|
| 2832CP | 0.00 | 0.000 | 2023-01-28 |
| 2833CP | 0.53 | 0.053 | 2023-01-28 |
| 2834CP | 1.06 | 0.106 | 2023-01-28 |
| 2835CP | 1.60 | 0.160 | 2023-01-28 |
| 2836CP | 5.32 | 0.532 | 2023-01-28 |
| 2837CP | 10.64 | 1.064 | 2023-01-28 |

EC REP

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