HIGH SENSITIVITY CRP CONTROL - LEVEL II (hsCRP CONTROL 2)

CAT. NO. CP 2477
SIZE: 10 x 1 ml
GTIN: 05055273201673
LOT NO. 2946CP
EXPIRY: 2025-01-28

INTENDED USE
Randox High Sensitivity CRP Control Level II is a ready to use control in a stabilised protein base. It is intended for use with the Randox High Sensitivity CRP Assay (Catalogue No. CP3885) for the control of accuracy and the control of reproducibility.

VALUE ASSIGNMENT
Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

Each batch of hsCRP Control is evaluated at Randox by latex-enhanced immunoturbidimetry with reference to materials standardized against the European Reference Material ERM®-DA474/IFCC. A lot specific value is given in the table below.

Lot No.	Target CRP Concentration		Range	
2946CP	4.09 (mg/l)	0.409 (mg/dl)	3.27 – 4.91 (mg/l)	0.327 – 0.491 (mg/dl)

PREPARATION
The Randox hsCRP Control is ready to use.

STABILITY
Unopened: The Randox hsCRP Control is stable up to the expiry date, when capped and stored at +2°C to +8°C.

Opened: Once opened, the Randox hsCRP Control 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 REQUIRED BUT NOT PROVIDED
Not Applicable

LIMITATIONS
The control should not be used as a calibration material. Residual control material should not be returned to the original container after use.

CHARACTERISTICS
The control 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.

SAFETY PRECAUTIONS AND WARNINGS
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.

This product has been developed for *in vitro* use only.

EC REP Randox Teoranta, Meenmore,
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