

LIQUID CRP CONTROL - LEVEL 2 (CRP CONTROL 2)

CAT. NO. CP 2480

LOT NO: 2646CP

SIZE: 10 x 1 ml

EXPIRY: 2021-01-28

GTIN: 05055273201703

INTENDED USE

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

SAFETY PRECAUTIONS AND WARNINGS

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

The control contains human CRP in a stabilised protein matrix. Human source material, from which this 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

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 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.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

OPENED: Store refrigerated (+2°C to +8°C). Once opened, the Randox Liquid CRP 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.

PREPARATION FOR USE

The CRP Control is supplied ready for use.

1. Mix by inversion at least 5 times to ensure homogeneity prior to use.
2. Refer to the control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Liquid CRP Control - Level 2 10 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

None.

ASSIGNED VALUES

A value (mean) has been assigned to this lot of control at Randox Laboratories Limited, using an immunoturbidimetric method. Traceability to ERM®-DA474/IFCC has been established.

The assigned value for this lot is listed in the table below.

Lot No.	Target CRP Concentration		Range	
	22.6 (mg/l)	2.26 (mg/dl)	18.1 - 27.1 (mg/l)	1.81 - 2.71 (mg/dl)
2646CP	22.6 (mg/l)	2.26 (mg/dl)	18.1 - 27.1 (mg/l)	1.81 - 2.71 (mg/dl)

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