

# IMMUNOGLOBULIN LIQUID PROTEIN CALIBRATOR (IG CAL)

FOR DILUTED SAMPLE ASSAYS

<b>CATALOGUE NO.</b>	IT 386I
<b>LOT NO.</b>	2174IT
<b>EXPIRY:</b>	2024-09-28
<b>PRESENTATION:</b>	Liquid
<b>SIZE:</b>	3 x 1 ml
<b>GTIN:</b>	05055273204056

## INTENDED USE

Liquid Protein Calibrators are *in vitro* diagnostic products for use with Randox IgA, IgG, IgM assays on the RX series analysers which require sample predilution.

## SAFETY PRECAUTIONS AND WARNINGS

The calibration material is derived from normal serum obtained from volunteer donors.

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), and Hepatitis C Virus (HCV) antibody 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.

Health and Safety Data Sheets are available on request.

**The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.**

## STORAGE AND STABILITY

The material is stable to expiry when stored at +2 to +8°C in the original capped containers. Open vials are stable for 30 days in the absence of bacterial contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

## PREPARATION FOR USE

For calibration of IgA, IgG and IgM the calibrators are ready for use as supplied.

## MATERIALS PROVIDED

Immunoglobulin Liquid Protein Calibrator (3 x 1 ml)

## MATERIALS REQUIRED BUT NOT PROVIDED

Pipette

## ASSIGNED VALUES

The assigned values below are for use on the RX **series** analysers with Randox immunoturbidimetric IgA, IgG and IgM kits using the sample dilution shown in the table.

	Reference Material	Sample Dilution	Units	Calibrator
IgA	ERM®-DA470k/IFCC	1 + 20	mg/dl	22.36
			g/l	0.224
IgG	ERM®-DA470k/IFCC	1 + 20	mg/dl	131.45
			g/l	1.315
IgM	ERM®-DA470k/IFCC	1 + 20	mg/dl	15.03
			g/l	0.150

EC REP Randox Teoranta, Meenmore,  
Dungloe, Donegal,  
F94 TV06, Ireland

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