

LIQUID PROTEIN CALIBRATORS (SP CAL (LIQ))

FOR NEAT SAMPLE ASSAYS

CATALOGUE NO.	IT 269I
LOT NOS.	1934IT - 1938IT
EXPIRY:	2021-06
PRESENTATION:	Liquid
SIZE:	5 x 1.0 ml
GTIN:	05055273204032

INTENDED USE

Liquid Protein Calibrators are an in vitro diagnostic product used for the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, Haptoglobin, IgA, IgG, IgM, Prealbumin, RF and Transferrin assays.

CHARACTERISTICS

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

Assignment of IT269I has been performed at Randox by immunoturbidimetry with reference to material standardised against appropriate International Reference Preparations. The assigned values for the batch are listed below.

PREPARATION

These Calibrators are supplied ready for use.

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.

SAFETY PRECAUTIONS AND WARNINGS

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.

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Saline Diluent, (Cat. No. SA 3854).

	REFERENCE MATERIAL	Units	Calibrator 1	Calibrator 2	Calibrator 3	Calibrator 4	Calibrator 5
ASO	NIBSC 97/662	IU/ml	-	-	-	-	566
Complement C3	ERM®-DA470k/IFCC	mg/dl	32.6	65.2	130.4	260.8	521.6
		g/l	0.33	0.65	1.30	2.61	5.22
Complement C4	ERM®-DA470k/IFCC	mg/dl	9.60	19.2	38.4	76.8	153.6
		g/l	0.10	0.19	0.38	0.77	1.54
CRP multipoint	ERM®-DA474/IFCC	mg/l	12.5	25.1	50.1	100.3	200.5
		g/l	0.0125	0.0251	0.0501	0.1003	0.2005
Ferritin	NIBSC 94/572	ng/ml	27.0	52.6	114.4	219.4	456.7
Haptoglobin	ERM®-DA470k/IFCC	mg/dl	23.2	46.4	92.8	185.5	371
		g/l	0.23	0.46	0.93	1.86	3.71
Ig A single point	ERM®-DA470k/IFCC	mg/dl	-	-	-	-	500
		g/l	-	-	-	-	5.00
IgG single point	ERM®-DA470k/IFCC	mg/dl	-	-	-	-	3525
		g/l	-	-	-	-	35.25
IgM single point	ERM®-DA470k/IFCC	mg/dl	-	-	-	-	368
		g/l	-	-	-	-	3.68
IgA multipoint	ERM®-DA470k/IFCC	mg/dl	31.3	62.5	125.0	250.0	500
		g/l	0.31	0.63	1.25	2.50	5.00
IgG multipoint	ERM®-DA470k/IFCC	mg/dl	220.3	440.6	881.3	1762.5	3525
		g/l	2.20	4.41	8.81	17.63	35.25
IgM multipoint	ERM®-DA470k/IFCC	mg/dl	23.0	46.0	92.0	184.0	368
		g/l	0.23	0.46	0.92	1.84	3.68
Prealbumin	ERM®-DA470k/IFCC	mg/dl	4.65	9.30	18.6	37.2	74.4
		g/l	0.05	0.09	0.19	0.37	0.74
Rheumatoid Factor	NIBSC 64/002	IU/ml	8.6	20.4	53.5	79.4	91.8
Transferrin	ERM®-DA470k/IFCC	mg/dl	32.2	64.5	128.9	257.9	515.7
		g/l	0.32	0.64	1.29	2.58	5.16

CALIBRATOR VALUES FOR RX SUZUKA AND RX MONACO

	REFERENCE MATERIAL	Units	Calibrator 1	Calibrator 2	Calibrator 3	Calibrator 4	Calibrator 5
IgA	ERM®-DA470k/IFCC	mg/dl	1.49	2.98	5.95	11.90	23.81
		g/l	0.015	0.030	0.060	0.119	0.238
IgG	ERM®-DA470k/IFCC	mg/dl	10.49	20.98	41.96	83.93	167.86
		g/l	0.105	0.210	0.420	0.839	1.679
IgM	ERM®-DA470k/IFCC	mg/dl	1.10	2.19	4.38	8.76	17.52
		g/l	0.011	0.022	0.044	0.088	0.175

Please note that 0.9% NaCl is required as the zero calibrator for ALL assays. We recommend Randox Saline Diluent, (Cat. No. SA 3854).

28 Jul 20 pl