LIPID CONTROL - LEVEL 1 (LPD CONTROL 1)

Cat. No. LE2661 **Lot No.** 2353CH
Size: 5 x 3 ml **Expiry:** 2018-03

INTENDED USE

This product is intended for *in vitro* use in the quality control of Direct HDL, Direct LDL, Lipoprotein (a), Apolipoprotein A-1, Apolipoprotein B, Cholesterol and Triglyceride methods on clinical chemistry systems.

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 (HIV1 & HIV2) antibody, Hepatitis B surface antigen (HbsAg) and the 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 disease. For *in vitro* diagnostic use only.

STORAGE AND STABILITY

Unopened Lipid Control is stable until the expiry date printed on the product label when stored between +2°C and +8°C. Once reconstituted, the components of the serum are stable for 7 days at +2°C to +8°C, and 4 weeks at –20°C when frozen once. The following exceptions apply: LP(a) is stable for 16 weeks at –20°C when frozen once. Values may drop by up to 10% for Direct LDL Cholesterol when stored for 4 weeks at –20°C.

PREPARATION FOR USE

Open the vial carefully, avoiding any loss of the material and reconstitute with 3 ml of distilled water. Replace the rubber stopper, close the vial and leave to stand for 30 minutes before use. Ensure that all traces of dry material are dissolved by swirling gently.

MATERIALS PROVIDED

Lipid Control - Level 1 5 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Distilled water
Volumetric pipette

VALUE ASSIGNMENT

Each batch of Lipid Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Apolipoprotein A-1	g/l	1.11	0.91	1.31	Immunoturbidimetric
	mg/dl	111	91.0	131	
	g/l	0.97	0.80	1.14	Nephelometric
	mg/dl	97.0	79.5	115	
Apolipoprotein B	g/l	0.85	0.70	1.00	Immunoturbidimetric
	mg/dl	85.0	69.7	100	
	g/l	0.82	0.67	0.97	Nephelometric
	mg/dl	82.0	67.2	96.8	
Cholesterol	mmol/l	3.81	3.31	4.31	Cholesterol Oxidase
	mg/dl	147	128	166	
	mmol/l	3.69	3.21	4.17	Siemens Dimension
	mg/dl	142	124	160	
	mmol/l	3.63	3.16	4.10	Ortho Vitros Microslide Systems
	mg/dl	140	122	158	
HDL - Cholesterol	mmol/l	0.77	0.66	0.89	Direct Clearance Method
	mg/dl	29.7	25.3	34.1	
	mmol/l	0.28	0.20	0.36	Phosphotungstic acid pptn.
	mg/dl	10.9	7.63	14.2	
	mmol/l	0.70	0.60	0.81	Direct HDL Immunoseparation
	mg/dl	27.0	23.0	31.0	
	mmol/l	0.61	0.52	0.70	Direct HDL PEGME
	mg/dl	23.5	20.0	27.0	
	mmol/l	0.77	0.66	0.89	Direct HDL PPD
	mg/dl	29.7	25.3	34.1	
	mmol/l	0.60	0.51	0.69	Direct HDL Roche 3rd generation
	mg/dl	23.2	19.7	26.7	
	mmol/l	0.72	0.61	0.83	Vitros dHDL PTA/MgCl2 direct precipitation
	mg/dl	27.8	23.5	32.1	
	mmol/l	0.82	0.70	0.94	HDL - Ultra
	mg/dl	31.7	27.0	36.4	
LDL - Cholesterol	mmol/l	2.28	1.94	2.62	Direct Clearance Method
	mg/dl	88.0	74.9	101	
	mmol/l	2.50	2.13	2.88	Calculated
	mg/dl	96.5	82.2	111	
	mmol/l	2.27	1.93	2.61	Selective detergent methods
	mg/dl	87.6	74.5	101	
Lipoprotein (a)	mg/dl	12.0	9.60	14.4	Immunoturbidimetric
	nmol/l	26.5	21.2	31.8	
Triglycerides	mmol/l	1.27	1.07	1.47	Lipase/GPO-PAP no correction
	mg/dl	112	94.7	129	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Triglycerides	mmol/l	1.44	1.21	1.67	Ortho Vitros Microslide Systems
	mg/dl	127	107	147	
	mmol/l	1.27	1.07	1.47	Lipase/GK UV no correction
	mg/dl	112	94.7	129	
	mmol/l	1.23	1.03	1.43	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	109	91.2	127	
	mmol/l	1.25	1.05	1.45	Lipase/Glycerol Dehydrogenase
	mg/dl	111	92.9	129	