

LIPID CONTROL - LEVEL I (LPD CONTROL I)

Cat. No. LE266 I **Lot No.** 2966CH
Size: 5 x 3 ml **Expiry:** 2025-03-28
GTIN: 05055273204155

INTENDED USE

This product is intended for *in vitro* use in the quality control of Direct HDL, Direct LDL, Lipoprotein (a), Apolipoprotein A-I, 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 I 5 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Distilled water
 Volumetric pipette

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 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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LIPID CONTROL - LEVEL 1 (LPD CONTROL 1)

Lot. No. 2966CH Cat. No. LE2661

Size 5 x 3ml Expiry 2025-03-28

Range

Analyte	unit	Target	low	high	methods	
Apolipoprotein A-1	g/l	1.00	0.82	1.18	Immunoturbidimetric	
	mg/dl	100	82.0	118		
	g/l	1.03	0.85	1.22	Nephelometric	
	mg/dl	103	84.5	122		
Apolipoprotein B	g/l	0.84	0.69	0.99	Immunoturbidimetric	
	mg/dl	83.6	68.6	98.6		
	g/l	0.83	0.68	0.98	Nephelometric	
	mg/dl	83.1	68.1	98.1		
Cholesterol	mmol/l	4.11	3.58	4.64	Cholesterol Oxidase - Abell Kendall	
	mg/dl	159	138	180		
	mmol/l	4.07	3.54	4.60	Siemens Dimension	
	mg/dl	157	137	177		
	mmol/l	4.13	3.59	4.67	Cholesterol Oxidase - IDMS	
	mg/dl	159	139	179		
	HDL - Cholesterol	mmol/l	0.89	0.76	1.02	Direct Clearance Method
		mg/dl	34.3	29.1	39.5	
mmol/l		0.34	0.29	0.39	Phosphotungstic acid pptn.	
mg/dl		13.1	11.1	15.1		
mmol/l		0.87	0.74	1.00	Direct HDL Immunoseparation	
mg/dl		33.6	28.6	38.6		
mmol/l		0.99	0.84	1.14	Direct HDL PEGME	
mg/dl		38.3	32.5	44.1		
mmol/l		1.02	0.87	1.17	Direct HDL PPD	
mg/dl		39.4	33.5	45.3		
mmol/l		0.88	0.74	1.01	Direct HDL Roche 4th Generation	
mg/dl		33.8	28.6	39.0		
mmol/l	1.02	0.87	1.17	HDL - Ultra		
mg/dl	39.4	33.6	45.2			
LDL - Cholesterol	mmol/l	2.56	2.18	2.94	Direct Clearance Method	
	mg/dl	98.8	84.1	114		
	mmol/l	2.44	2.07	2.81	Calculated	
	mg/dl	94.2	79.9	109		
	mmol/l	2.35	2.00	2.70	Selective detergent methods	
	mg/dl	90.7	77.2	104		
Lipoprotein (a)	mg/dl	19.2	15.4	23.0	Immunoturbidimetric	
	nmol/l	33.6	26.9	40.3		
Triglycerides	mmol/l	1.51	1.27	1.75	Lipase/GPO-PAP no correction	
	mg/dl	134	112	156		
	mmol/l	1.53	1.29	1.77	Lipase/GK UV no correction	
	mg/dl	135	114	156		

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Lot. No. 2966CH Cat. No. LE2661

Size 5 x 3ml Expiry 2025-03-28

Range

Analyte	unit	Target	low	high	methods
Triglycerides	mmol/l	1.54	1.29	1.79	Lipase/Glycerol Dehydrogenase
	mg/dl	136	114	158	