

LIPID CONTROL - LEVEL 2 (LPD CONTROL 2)

Cat. No. LE2662

Lot No. 2877CH

Size: 5 x 3 ml

Expiry: 2024-02-28

GTIN: 05055273204162

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 2 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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Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

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Range

Analyte	unit	Target	low	high	methods	
Apolipoprotein A-1	g/l	1.53	1.25	1.81	Immunoturbidimetric	
	mg/dl	153	125	181		
	g/l	1.50	1.23	1.77	Nephelometric	
	mg/dl	150	123	177		
Apolipoprotein B	g/l	1.11	0.91	1.31	Immunoturbidimetric	
	mg/dl	111	91.0	131		
	g/l	1.20	0.98	1.42	Nephelometric	
	mg/dl	120	98.4	142		
Cholesterol	mmol/l	5.52	4.80	6.24	Cholesterol Oxidase - Abell Kendall	
	mg/dl	213	185	241		
	mmol/l	5.36	4.66	6.06	Siemens Dimension	
	mg/dl	207	180	234		
	mmol/l	5.56	4.84	6.28	Cholesterol Oxidase - IDMS	
	mg/dl	215	187	243		
HDL - Cholesterol	mmol/l	1.31	1.11	1.51	Direct Clearance Method	
	mg/dl	50.6	42.8	58.4		
	mmol/l	0.86	0.60	1.11	Phosphotungstic acid pptn.	
	mg/dl	33.0	23.1	42.9		
	mmol/l	1.24	1.05	1.43	Direct HDL Immunoseparation	
	mg/dl	47.9	40.5	55.3		
	mmol/l	1.23	1.05	1.41	Direct HDL PEGME	
	mg/dl	47.5	40.5	54.5		
	mmol/l	1.46	1.24	1.68	Direct HDL PPD	
	mg/dl	56.4	47.9	64.9		
LDL - Cholesterol	mmol/l	1.19	1.01	1.37	Direct HDL Roche 4th Generation	
	mg/dl	45.9	39.0	52.8		
	mmol/l	1.46	1.24	1.68	HDL - Ultra	
	mg/dl	56.4	47.9	64.9		
	LDL - Cholesterol	mmol/l	3.57	3.03	4.11	Direct Clearance Method
		mg/dl	138	117	159	
		mmol/l	3.12	2.65	3.59	Calculated
		mg/dl	120	102	138	
LDL - Cholesterol	mmol/l	3.06	2.60	3.52	Selective detergent methods	
	mg/dl	118	100	136		
	Lipoprotein (a)	mg/dl	21.1	16.9	25.3	Immunoturbidimetric
		nmol/l	36.2	29.0	43.4	
Triglycerides	mmol/l	2.33	1.96	2.70	Lipase/GPO-PAP no correction	
	mg/dl	206	173	239		
	mmol/l	2.30	1.93	2.67	Lipase/GK UV no correction	
	mg/dl	204	171	237		