

LIPID CONTROL - LEVEL 2 (LPD CONTROL 2)

CAT. NO. LE2662

LOT NO. 2723CH

SIZE: 5 x 3 ml

EXPIRY: 2022-06-28

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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Range

Analyte	unit	Target	low	high	methods	
Apolipoprotein A-1	g/l	1.52	1.25	1.79	Immunoturbidimetric	
	mg/dl	152	125	179		
	g/l	1.54	1.26	1.82	Nephelometric	
	mg/dl	154	126	182		
Apolipoprotein B	g/l	1.11	0.91	1.31	Immunoturbidimetric	
	mg/dl	111	91.0	131		
	g/l	1.21	0.99	1.43	Nephelometric	
	mg/dl	121	99.0	143		
Cholesterol	mmol/l	5.17	4.50	5.84	Siemens Dimension	
	mg/dl	200	174	226		
	mmol/l	5.33	4.64	6.02	Cholesterol Oxidase - Abell Kendall	
	mg/dl	206	179	233		
	mmol/l	5.26	4.58	5.94	Cholesterol Oxidase - IDMS	
	mg/dl	203	177	229		
	HDL-Cholesterol	mmol/l	1.25	1.06	1.44	Direct Clearance Method
		mg/dl	48.3	40.9	55.7	
mmol/l		0.74	0.52	0.96	Phosphotungstic acid pptn.	
mg/dl		28.4	19.9	36.9		
mmol/l		1.15	0.98	1.32	Direct HDL Immunoseparation	
mg/dl		44.4	37.8	51.0		
mmol/l		1.18	1.00	1.36	Direct HDL PEGME	
mg/dl		45.5	38.6	52.4		
	mmol/l	1.42	1.21	1.63	Direct HDL PPD	
	mg/dl	54.8	46.7	62.9		
	mmol/l	1.14	0.97	1.31	Direct HDL Roche 4th Generation	
	mg/dl	44.0	37.4	50.6		
	mmol/l	1.40	1.19	1.61	HDL - Ultra	
	mg/dl	54.0	45.9	62.1		
LDL-Cholesterol	mmol/l	3.56	3.03	4.09	Direct Clearance Method	
	mg/dl	137	117	157		
	mmol/l	3.01	2.56	3.46	Calculated	
	mg/dl	116	98.8	133		
	mmol/l	3.11	2.64	3.58	Selective detergent methods	
	mg/dl	120	102	138		
Lipoprotein (a)	mg/dl	20.6	16.5	24.7	Immunoturbidimetric	
	nmol/l	40.5	32.4	48.6		
Triglycerides	mmol/l	2.18	1.83	2.53	Lipase/GPO-PAP no correction	
	mg/dl	193	162	224		
	mmol/l	2.18	1.83	2.53	Lipase/GK UV no correction	
	mg/dl	193	162	224		