LIPID CONTROL - LEVEL 2 (LPD CONTROL 2)

Cat. No. LE2669
Size: 5 x 1 ml
GTIN: 05055273204193
Lot No. 2989CH
Expiry: 2024-02-28

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 1 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 1 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.

EC REP Randox Teoranta, Meenmore,
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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	
	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	
	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	