LIPID CONTROL - LEVEL 3 (LPD CONTROL 3)

Cat. No. LE2663 **Lot No.** 3222CH
Size: 5 x 3 ml **Expiry:** 2028-09-28
GTIN: 05055273204179

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

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Pictogram



Warning

Hazard statement(s)
H317 - May cause an allergic skin reaction.

Precautionary statement(s)
Avoid breathing dust/fume/gas/mist/vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of water.
If skin irritation or rash occurs: Get medical advice/attention
Dispose of contents/container according to local and national guidelines

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 3 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.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

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Method 2

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Method							Lipid Control - Level 3 (LPD CONTROL 3)
Lot. No: 3222CH Cat. No: LE2663 Expiry: 2028/09/28							
Size: 5 x 3 ml			Range				
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Apolipoprotein A1	g/l	1.74	1.43	2.05	0.155	0.310	Nephelometric (Non IFCC Cal.)
	mg/dl	174	143	205	15.5	31.0	
	g/l	1.79	1.47	2.11	0.160	0.320	Turbidimetric (IFCC Cal.)
	mg/dl	179	147	211	16.0	32.0	
Apolipoprotein B	g/l	1.38	1.13	1.63	0.125	0.250	Nephelometric Assays
	mg/dl	138	113	163	12.5	25.0	
	g/l	1.48	1.21	1.75	0.135	0.270	Turbidimetric Assays
	mg/dl	148	121	175	13.5	27.0	
Cholesterol Total	mg/dl	274	233	315	20.5	41.0	Abbott Alinity Cholesterol 2
	mmol/l	7.09	6.03	8.15	0.530	1.06	
	mg/dl	273	232	314	20.5	41.0	Abbott Architect Cholesterol 2
	mmol/l	7.07	6.01	8.13	0.530	1.06	
	mg/dl	273	232	314	20.5	41.0	Cholesterol Oxidase - Abell Kendall
	mmol/l	7.08	6.02	8.14	0.530	1.06	
	mg/dl	278	236	320	21.0	42.0	Cholesterol Oxidase - IDMS
	mmol/l	7.21	6.13	8.29	0.540	1.08	
HDL - Cholesterol	mg/dl	61.4	52.2	70.6	4.60	9.20	Direct HDL, Clearance method
	mmol/l	1.59	1.35	1.83	0.120	0.240	
	mg/dl	58.3	49.6	67.0	4.35	8.70	Direct HDL, Immunoseparation
	mmol/l	1.51	1.28	1.74	0.115	0.230	
	mg/dl	52.5	44.6	60.4	3.95	7.90	Direct HDL, PEGME
	mmol/l	1.36	1.16	1.56	0.100	0.200	
	mg/dl	64.9	55.2	74.6	4.85	9.70	Direct HDL, PPD
	mmol/l	1.68	1.43	1.93	0.125	0.250	
	mg/dl	52.1	44.3	59.9	3.90	7.80	Direct HDL, Roche 4th gen.
	mmol/l	1.35	1.15	1.55	0.100	0.200	
	mg/dl	67.2	57.1	77.3	5.05	10.1	HDL Ultra/Accel Selective Detergent
	mmol/l	1.74	1.48	2.00	0.130	0.260	
LDL Cholesterol	mg/dl	144	122	166	11.0	22.0	Calculated
	mmol/l	3.72	3.16	4.28	0.280	0.560	
	mg/dl	154	131	177	11.5	23.0	Other direct methods
	mmol/l	3.98	3.38	4.58	0.300	0.600	
	mg/dl	172	146	198	13.0	26.0	Sel.detergent Beckman OSR6x83
	mmol/l	4.45	3.78	5.12	0.335	0.670	
	mg/dl	132	112	152	10.0	20.0	Sel.detergent Beckman OSR6x96
	mmol/l	3.41	2.90	3.92	0.255	0.510	
	mg/dl	149	127	171	11.0	22.0	Selective Detergent Methods
	mmol/l	3.86	3.28	4.44	0.290	0.580	

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All enzyme values are quoted to a temperature of 37°C, unless otherwise stated

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Method							Lipid Control - Level 3 (LPD CONTROL 3)
Lot. No: 3222CH Cat. No: LE2663 Expiry: 2028/09/28							
Size: 5 x 3 ml			Range				
Analyte	**Unit**	**Target**	**Low**	**High**	**1SD**	**2SD**	**Method**
LDL Cholesterol	mg/dl	142	121	163	10.5	21.0	Siemens Atellica LDLC
	mmol/l	3.67	3.12	4.22	0.275	0.550	
Lipoprotein (a) mg/dl	mg/dl	30.0	24.0	36.0	3.00	6.00	Immunoturbidimetric
Lipoprotein (a) nmol/l	nmol/l	56.5	45.2	67.8	5.65	11.3	Immunoturbidimetric
Triglycerides	mg/dl	337	286	388	25.5	51.0	Abbott Alinity i
	mmol/l	3.81	3.24	4.38	0.285	0.570	
	mg/dl	340	289	391	25.5	51.0	Lipase/GK UV. no correction
	mmol/l	3.84	3.26	4.42	0.290	0.580	
	mg/dl	337	286	388	25.5	51.0	Lipase/Glycerol Dehydrogenase
	mmol/l	3.81	3.24	4.38	0.285	0.570	
	mg/dl	337	286	388	25.5	51.0	Lipase/GPO-PAP No Correction
	mmol/l	3.81	3.24	4.38	0.285	0.570	

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