

LIPID CONTROL - LEVEL 3 (LPD CONTROL 3)

Cat. No. LE2670 **Lot No.** 3120CH
Size: 5 x 1 ml **Expiry:** 2027-05-28
GTIN: 05055273204209

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 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 3 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.

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Method		Lipid Control - Level 3 (LPD CONTROL 3)					
Lot. No: 3120CH Cat. No: LE2670 Expiry: 2027/05/28							
Size: 5 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Apolipoprotein A1	g/l	2.06	1.69	2.43	0.185	0.370	Nephelometric (Non IFCC Cal.)
	mg/dl	206	169	243	18.5	37.0	
	g/l	1.96	1.61	2.31	0.175	0.350	Turbidimetric (IFCC Cal.)
	mg/dl	196	161	231	17.5	35.0	
Apolipoprotein B	g/l	1.43	1.17	1.69	0.130	0.260	Nephelometric Assays
	mg/dl	143	117	169	13.0	26.0	
	g/l	1.47	1.21	1.73	0.130	0.260	Turbidimetric Assays
	mg/dl	147	121	173	13.0	26.0	
Cholesterol Total	mg/dl	290	247	333	21.5	43.0	Abbott Alinity Cholesterol 2
	mmol/l	7.51	6.38	8.64	0.565	1.13	
	mg/dl	285	242	328	21.5	43.0	Cholesterol Oxidase - Abell Kendall
	mmol/l	7.38	6.27	8.49	0.555	1.11	
	mg/dl	291	247	335	22.0	44.0	Cholesterol Oxidase - IDMS
	mmol/l	7.54	6.41	8.67	0.565	1.13	
HDL - Cholesterol	mg/dl	78.8	67.0	90.6	5.90	11.8	Direct HDL, Clearance method
	mmol/l	2.04	1.73	2.35	0.155	0.310	
	mg/dl	67.6	57.5	77.7	5.05	10.1	Direct HDL, Immunoseparation
	mmol/l	1.75	1.49	2.01	0.130	0.260	
	mg/dl	66.0	56.1	75.9	4.95	9.90	Direct HDL, PEGME
	mmol/l	1.71	1.45	1.97	0.130	0.260	
	mg/dl	81.1	68.9	93.3	6.10	12.2	Direct HDL, PPD
	mmol/l	2.10	1.79	2.41	0.155	0.310	
	mg/dl	62.9	53.5	72.3	4.70	9.40	Direct HDL, Roche 4th gen.
	mmol/l	1.63	1.39	1.87	0.120	0.240	
	mg/dl	80.3	68.3	92.3	6.00	12.0	HDL Ultra/Accel Selective Detergent
	mmol/l	2.08	1.77	2.39	0.155	0.310	
LDL Cholesterol	mg/dl	188	160	216	14.0	28.0	Direct Clearance Method
	mmol/l	4.87	4.14	5.60	0.365	0.730	
	mg/dl	142	121	163	10.5	21.0	Calculated
	mmol/l	3.68	3.13	4.23	0.275	0.550	
	mg/dl	168	143	193	12.5	25.0	Sel.detergent Beckman OSR6x83
	mmol/l	4.36	3.71	5.01	0.325	0.650	
	mg/dl	159	135	183	12.0	24.0	Sel.detergent Beckman OSR6x96
	mmol/l	4.11	3.49	4.73	0.310	0.620	
	mg/dl	164	139	189	12.5	25.0	Selective Detergent Methods
	mmol/l	4.25	3.61	4.89	0.320	0.640	
	mg/dl	158	134	182	12.0	24.0	Siemens Atellica LDLC
	mmol/l	4.10	3.49	4.71	0.305	0.610	

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Size: 5 x 1 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Lipoprotein (a) mg/dl	mg/dl	31.3	25.0	37.6	3.15	6.30	Immunoturbidimetric
Lipoprotein (a) nmol/l	nmol/l	59.6	47.7	71.5	5.95	11.9	Immunoturbidimetric
Triglycerides	mg/dl	372	316	428	28.0	56.0	Abbott Alinity i
	mmol/l	4.20	3.57	4.83	0.315	0.630	
	mg/dl	369	314	424	27.5	55.0	Lipase/GK UV. no correction
	mmol/l	4.17	3.54	4.80	0.315	0.630	
	mg/dl	376	320	432	28.0	56.0	Lipase/Glycerol Dehydrogenase
	mmol/l	4.25	3.61	4.89	0.320	0.640	
	mg/dl	377	320	434	28.5	57.0	Lipase/GPO-PAP No Correction
	mmol/l	4.26	3.62	4.90	0.320	0.640	
mg/dl	360	306	414	27.0	54.0	Siemens Atellica IM	
mmol/l	4.07	3.46	4.68	0.305	0.610		
mg/dl	369	314	424	27.5	55.0	Siemens Dimension	
mmol/l	4.17	3.54	4.80	0.315	0.630		