



# **LIPID CONTROL - LEVEL 3 (LPD CONTROL 3)**

 Cat. No.
 LE2663
 Lot No.
 3011CH

 Size:
 5 x 3 ml
 Expiry:
 2025-11-28

**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-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  $+2^{\circ}$ C and  $+8^{\circ}$ C. Once reconstituted, the components of the serum are stable for 7 days at  $+2^{\circ}$ C to  $+8^{\circ}$ C, and 4 weeks at  $-20^{\circ}$ C when frozen once. The following exceptions apply: LP(a) is stable for 16 weeks at  $-20^{\circ}$ C when frozen once. Values may drop by up to 10% for Direct LDL Cholesterol when stored for 4 weeks at  $-20^{\circ}$ 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 <u>Technical Services@randox.com</u>.

EC REP

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

Rev. 18 Jul '23 me



LIPID CONTROL - LEVEL 3 (LPD CONTROL 3)  Lot. No. 3011CH Cat. No. LE2663  Sinc. 5 v. 2 ml. Evrsim: 2025 44 29					
Analyte	unit	Target	low	high	methods
Apolipoprotein A-1  Apolipoprotein B	g/I	1.88	1.54	2.22	Immunoturbidimetric
	mg/dl	188	154	222	No. 1 de la companya
	g/I	1.87	1.53	2.21	Nephelometric
	mg/dl	187	153	221	
	g/I	1.65	1.35	1.95	Immunoturbidimetric
	mg/dl	165	135	195	N. I. I. A.
	g/I	1.65	1.35	1.95	Nephelometric
	mg/dl	165	135	195	Object of the Constitution
HDL - Cholesterol	mmol/l	7.97	6.93	9.01	Cholesterol Oxidase - Abell Kendall
	mg/dl	308	267	349	Oi-man Dimension
	mmol/l	7.89	6.86	8.92	Siemens Dimension
	mg/dl	305	265	345	Obstantant Oridors IDMO
	mmol/l	8.09	7.04	9.14	Cholesterol Oxidase - IDMS
	mg/dl	312	272	352	Disease Olegania Mathematic
	mmol/l	1.80	1.53	2.07	Direct Clearance Method
	mg/dl mmol/l	69.5	59.1	79.9	Disast LIDI Insurum accumentium
		1.73 66.8	1.47 56.7	1.99 76.9	Direct HDL Immunoseparation
	mg/dl mmol/l	1.58	1.34	1.82	Direct HDL PEGME
	mg/dl	61.0	51.7	70.3	DIIECT FEGIVIE
	mmol/l	1.90	1.62	2.19	Direct HDL PPD
	mg/dl	73.3	62.5	84.1	DIIECT HDE PPD
	mmol/l	1.51	1.28	1.74	Direct HDL Roche 4th Generation
	mg/dl	58.3	49.4	67.2	Direct FIDE Roche 4th Generation
	mmol/l	1.89	1.61	2.17	HDL - Ultra
	mg/dl	73.0	62.1	83.9	TIDE - Ollia
	mmol/l	1.45	1.23	1.67	Phosphotungstic acid pptn.
	mg/dl	56.0	47.5	64.5	i nosphotaligatic acid pptil.
LDL - Cholesterol	mmol/l	4.20	3.57	4.83	Calculated
	mg/dl	162	138	186	Galdulated
	mmol/l	4.53	3.85	5.21	Selective detergent methods
	mg/dl	175	149	201	ociocave detergent methods
	mmol/l	5.32	4.52	6.12	Direct Clearance Method
	mg/dl	205	174	236	5 Old Idiano Monida
Lipoprotein (a)	mg/dl	35.4	28.3	42.5	Immunoturbidimetric
	nmol/l	67.9	54.3	81.5	
Triglycerides	mmol/l	4.43	3.72	5.14	Lipase/GPO-PAP no correction
	mg/dl	392	329	455	2.p200701 0 174 110 0011004011
	mmol/l	4.40	3.70	5.10	Lipase/GK UV no correction
	mg/dl	389	327	451	



#### **LIPID CONTROL - LEVEL 3 (LPD CONTROL 3)** Lot. No. 3011CH Cat. No. LE2663 Range Size 5 x 3 ml Expiry 2025-11-28 Analyte unit **Target** low high methods Triglycerides 4.50 3.78 Lipase/Glycerol Dehydrogenase mmol/l 5.22

461

398

mg/dl

335