



## PRODUCT INFORMATION

LE2668

3008CH

Please note that in Lipid Control Level 1 lot 3008CH, no value is present for HDL Cholesterol - Phosphotungstic acid pptn. This will be updated in due course.

INC16

## LIPID CONTROL - LEVEL I (LPD CONTROL I)

**Cat. No.** LE2668                      **Lot No.** 3008CH  
**Size:** 5 x 1 ml                      **Expiry:** 2025-11-28  
**GTIN:** 05055273204186

### 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 I 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](mailto:Technical.Services@randox.com).

EC	REP
----	-----

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

Rev. 08 May '23 me

## LIPID CONTROL - LEVEL 1 (LPD CONTROL 1)

Lot. No. 3008CH Cat. No. LE2668

Size 5 x 1 ml Expiry 2025-11-28

Range

Analyte	unit	Target	low	high	methods	
Apolipoprotein A-1	g/l	0.91	0.75	1.07	Immunoturbidimetric	
	mg/dl	91.0	74.6	107		
	g/l	0.91	0.75	1.07	Nephelometric	
	mg/dl	91.0	74.6	107		
Apolipoprotein B	g/l	0.81	0.66	0.95	Immunoturbidimetric	
	mg/dl	80.5	66.0	95.0		
	g/l	0.83	0.68	0.98	Nephelometric	
	mg/dl	82.7	67.8	97.6		
Cholesterol	mmol/l	3.86	3.36	4.36	Cholesterol Oxidase - Abell Kendall	
	mg/dl	149	130	168		
	mmol/l	3.90	3.39	4.41	Siemens Dimension	
	mg/dl	151	131	171		
	mmol/l	3.90	3.39	4.41	Ortho Vitros Microslide Systems	
	mg/dl	151	131	171		
	mmol/l	3.87	3.37	4.37	Cholesterol Oxidase - IDMS	
	mg/dl	149	130	168		
HDL - Cholesterol	mmol/l	0.79	0.67	0.91	Direct Clearance Method	
	mg/dl	30.4	25.8	35.0		
	mmol/l	0.81	0.69	0.93	Direct HDL Immunoseparation	
	mg/dl	31.2	26.6	35.8		
	mmol/l	0.90	0.77	1.04	Direct HDL PEGME	
	mg/dl	34.8	29.6	40.0		
	mmol/l	0.94	0.80	1.08	Direct HDL PPD	
	mg/dl	36.4	31.0	41.8		
LDL - Cholesterol	mmol/l	0.77	0.65	0.88	Direct HDL Roche 4th Generation	
	mg/dl	29.6	25.1	34.1		
	mmol/l	0.91	0.78	1.05	HDL - Ultra	
	mg/dl	35.2	30.1	40.3		
	LDL - Cholesterol	mmol/l	2.41	2.05	2.77	Calculated
		mg/dl	93.0	79.1	107	
		mmol/l	2.23	1.90	2.56	Selective detergent methods
		mg/dl	86.1	73.3	98.9	
mmol/l		2.41	2.05	2.77	Direct Clearance Method	
mg/dl		93.0	79.1	107		
Lipoprotein (a)	mg/dl	18.6	14.9	22.3	Immunoturbidimetric	
	nmol/l	34.0	27.2	40.8		
Triglycerides	mmol/l	1.27	1.07	1.47	Lipase/GPO-PAP no correction	
	mg/dl	112	94.7	129		
	mmol/l	1.28	1.07	1.48	Ortho Vitros Microslide Systems	
	mg/dl	113	94.7	131		

## LIPID CONTROL - LEVEL 1 (LPD CONTROL 1)

Lot. No. 3008CH Cat. No. LE2668

Size 5 x 1 ml Expiry 2025-11-28

Range

Analyte	unit	Target	low	high	methods
Triglycerides	mmol/l	1.27	1.06	1.47	Lipase/GK UV no correction
	mg/dl	112	93.8	130	
	mmol/l	1.33	1.12	1.54	Lipase/Glycerol Dehydrogenase
	mg/dl	118	99.0	137	