

## APOLIPOPROTEIN CONTROL - LEVEL 3 (APO CONTROL 3)

**CAT. NO.** LE5018 **LOT NO.** 2917CH  
**SIZE** 3 x 1 ml **EXPIRY:** 2024-02-28  
**GTIN:** 05055273209129

### INTENDED USE

This product is intended for *in-vitro* use in the quality control of Apolipoprotein A-II, Apolipoprotein C-II, Apolipoprotein C-III, Apolipoprotein E 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 Apolipoprotein Control is stable until the expiry date printed on the product label when stored between +2°C and +8°C.

Once reconstituted, Apo All, Apo CII and Apo CIII are stable for 7 days at +2°C to +8°C and Apo E is stable for 8 hours at +2°C to +8°C.

The components of the serum are also stable for 28 days at -20°C when frozen once.

### 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

Apolipoprotein Control - Level 3 3 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 Apolipoprotein 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.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

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

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**APOLIPOPROTEIN CONTROL - LEVEL 3 (APO CONTROL 3)**

Lot. No. 2917CH    Cat. No. LE5018

Size 3 x 1ml    Expiry 2024-02-28    Range

Analyte	unit	Target	low	high	methods
Apolipoprotein A-II	g/l	0.422	0.030	0.055	Immunoturbidimetric
	mg/dl	42.2	29.5	54.9	
Apolipoprotein C-II	g/l	0.045	0.031	0.058	Immunoturbidimetric
	mg/dl	4.46	3.12	5.80	
Apolipoprotein C-III	g/l	0.122	0.085	0.159	Immunoturbidimetric
	mg/dl	12.2	8.50	15.9	
Apolipoprotein E	g/l	0.034	0.024	0.044	Immunoturbidimetric
	mg/dl	3.40	2.38	4.42	