

## APOLIPOPROTEIN CALIBRATOR (APO CAL)

**CATALOGUE NO.** LP3023  
**LOT NO.** 1069LP  
**EXPIRY:** 2018 – 02  
**PRESENTATION:** Lyophilised  
**SIZE:** 3 x 1 ml

### INTENDED USE:

This product is intended for in-vitro use in the calibration of Apolipoprotein A-I and Apolipoprotein B.

### 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 calibrator is stable until the expiry date printed on the product label when stored between +2°C and +8°C.

Once reconstituted APO A-I and APO B are stable for 7 days at +2°C to +8°C, and 1 month 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 calibrator

### MATERIALS REQUIRED BUT NOT PROVIDED:

Distilled water

Pipette capable of accurate measurement at 1000 µl

APO A-I and APO B calibration has been performed at Randox by immunoturbidimetry with reference material standardised against WHO/IFCC Reference Standard. The assigned values for the batch are listed below.

	g/l	mg/dl
APOLIPOPROTEIN A-I	2.27	227
APOLIPOPROTEIN B	2.19	219

### PREPARATION OF STANDARD SERIES ON

#### RX series INSTRUMENTATION

RX **daytona** and RX **imola** analysers can prepare a standard series from a single standard but cannot perform a 1+1 dilution for this series. The following corrected values for automatic dilution should be entered if using a RX **daytona** and RX **imola** analyser to create the standard series. Values are obtained by multiplying the top calibrator by appropriate dilution factor.

DILUTION FACTOR	SALINE	0.125	0.25	0.4375	NIL
APO A-I (mg/dl)	0	28.375	56.75	99.3125	227
APO B (mg/dl)	0	27.375	54.75	95.8125	219

RX **suzuka** analysers can prepare a standard series from a single standard, starting with a 1/9.4 (1+8.4) dilution.

Accordingly, you should program the appropriate analyser with the following standard values when using sample dilutions of 1/21 (1 + 20).

	DILUTION	1/150 1+149	1/75 1+74	1/37.5 1+36.5	1/18.75 1+17.75	1/9.4 1+8.4
approx. dilution factor of neat std.		0.14	0.28	0.56	1.12	2.24
APO A-I	mg/dl	1.51333	3.02667	6.05333	12.1067	24.1489
APO B	mg/dl	1.46	2.92	5.84	11.68	23.2979

### COBAS MIRA or COBAS MIRA- S SYSTEM

	g/l	mg/dl
APOLIPOPROTEIN A-I	47.67	4767
APOLIPOPROTEIN b	45.99	4599

### CALIBRATOR SERIAL DILUTIONS FOR NEAT

**SAMPLE ANALYSIS:** (For use on any instrument on which samples are **NOT** diluted either manually or automatically.)

	S1	S2	S3	S4	S5
Dilution	Saline	1+7	1+3	1+1	Nil
APO A-I (mg/dl)	0	28.375	56.75	113.5	227
APO B (mg/dl)	0	27.375	54.75	109.5	219

Prepare a standard series according to the following scheme and program the instrument with the following values:

**N.B.** The Hitachi 911 can prepare a standard series from a single standard. Please ensure that the correct ratio of sample to diluent is entered in the calibration table. If a manually diluted calibrator series is used please ensure that the S.VOL for STD 1-5 is 2 µl and that PRE. DIL VOLs are all zero.

**CALIBRATOR SERIAL DILUTIONS FOR DILUTED SAMPLE ANALYSIS ON THE KONELAB** (This analyser automatically applies the sample dilution to the final reported result.)

Dilute the calibrator with 0.9 % (w/v) NaCl solution in a geometric series, starting with a ratio of 9.4 (1 + 8.4) before applying to the instrument for automated geometric series generation.

Accordingly, you should program the appropriate analyser with the following standard values when using sample dilutions of 1/21 (1 + 20).

	DILUTION	1/150 1+149	1/75 1+74	1/37.5 1+36.5	1/18.75 1+17.75	1/9.4 1+8.4
approx. dilution factor of neat std.		0.14	0.28	0.56	1.12	2.24
APO A-I	mg/dl	1.51333	3.02667	6.05333	12.1067	24.1489
APO B	mg/dl	1.46	2.92	5.84	11.68	23.2979

**CALIBRATOR SERIAL DILUTIONS FOR DILUTED SAMPLE ANALYSIS** (for manual use and on any instrument on which calibrators are NOT diluted automatically)

**NB** Including systems with automatic sample dilution.

Dilute the calibrator with 0.9 % (w/v) NaCl solution in a geometric series, starting with a ratio of 9.4 (1 + 8.4).

Accordingly, you should program the appropriate analyser with the following standard values when using samples dilutions of 1/21 (1 + 20).

	DILUTION	1/150 1+149	1/75 1+74	1/37.5 1+36.5	1/18.75 1+17.75	1/9.4 1+8.4
approx. dilution factor of neat std.		0.14	0.28	0.56	1.12	2.24
APO A-I	mg/dl	31.78	63.56	127.12	254.24	508.48
APO B	mg/dl	30.66	61.32	122.64	245.28	490.56

**CALIBRATOR SERIAL DILUTIONS FOR DILUTED SAMPLE ANALYSIS** (for use on any instrument on which samples AND CALIBRATORS are diluted automatically)

Prepare a standard series according to the following scheme and program the instrument with the following values:

	S1	S2	S3	S4	S5
Dilution	Saline	1+7	1+3	1+1	Neat
APO A-I (mg/dl)	0	28.375	56.75	113.5	227
APO B (mg/dl)	0	27.375	54.75	109.5	219

12 March 15 em