

APOLIPOPROTEIN CALBRATOR (APO CAL)

CATALOGUE NO. LP3023
LOT NO. 1616LP
EXPIRY: 2024-10-28
PRESENTATION: Lyophilised
SIZE: 3 x 1 ml
GTIN: 05055273204414

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	2.45	245
APOLIPOPROTEIN B	2.01	201

PREPARATION OF STANDARD SERIES ON RX series INSTRUMENTATION

RX **Daytona**, RX **imola**, RX **daytona plus** and RX **modena** 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**, RX **imola**, RX **daytona plus** or RX **modena** 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	30.625	61.25	107.188	245
APO B (mg/dl)	0	25.125	50.25	87.9375	201

RX **suzuka** and RX **monaco** 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	1.63333	3.26667	6.53333	13.0667	26.0638
APO B	mg/dl	1.34	2.68	5.36	10.72	21.3830

COBAS MIRA or COBAS MIRA- S SYSTEM

	g/l	mg/dl
APOLIPOPROTEIN A-I	51.45	5145
APOLIPOPROTEIN b	42.21	4221

CALBRATOR 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	30.625	61.25	122.5	245
APO B (mg/dl)	0	25.125	50.25	100.5	201

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	1.63333	3.26667	6.53333	13.0667	26.0638
APO B	mg/dl	1.34	2.68	5.36	10.72	21.3830

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	34.3	68.6	137.2	274.4	548.8
APO B	mg/dl	28.14	56.28	112.56	225.12	450.24

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

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	30.625	61.25	122.5	245
APO B (mg/dl)	0	25.125	50.25	100.5	201

25 Jan '22 me