

Art.-Nr.: KG3023
Ch.-B.: 633LP
Inhalt: 1 ml
Verw. bis: 2011-09
Darreichungsform: Lyophilised
Produkt Nr.: LP005

INTENDED USE:

This product is intended for in-vitro use in the calibration of Apolipoprotein A-I, Apolipoprotein B, Apolipoprotein A-II, Apolipoprotein E, Apolipoprotein C-II, and Apolipoprotein C-III

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 6 months at -20°C when frozen once, 28 days at 2°C to 8°C for APO A-II and APO C-III, 14 days at 2°C to 8°C for APO C-II, 1 day at 2°C to 8°C for APO E 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 (3 x 1ml)

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 BGT 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	2.29	229
APOLIPOPROTEIN B	2.20	220
APOLIPOPROTEIN A-II	0.444	44.4
APOLIPOPROTEIN C-II	0.085	8.52
APOLIPOPROTEIN C-III	0.170	17.0
APOLIPOPROTEIN E	0.040	4.03

THIS SECTION IS APPLICABLE TO APOLIPOPROTEIN A-I AND APOLIPOPROTEIN B ONLY

COBAS MIRA or COBAS MIRA-S SYSTEM

	g/l	mg/dl
APOLIPOPROTEIN A-1	48.09	4809
APOLIPOPROTEIN B	46.20	4620

CALIBRATOR SERIAL DILUTIONS FOR NEAT SAMPLE ANALYSIS: (For use on any instrument on which samples are NOT diluted either manually or automatically.)

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

	S1	S2	S3	S4	S5
Dilution	Saline	1+7	1+3	1+1	Nil
A-I (mg/dl)	0	28.63	57.25	114.5	229
B (mg/dl)	0	27.5	55.0	110	220

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.

PREPARATION OF STANDARD SERIES ON rxseries INSTRUMENTATION

rxseries instrumentation 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 rxseries instrumentation to create the standard series. This is only applicable to APO A-I and APO B.

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	28.625	57.25	100.188	229
APO B	0	27.5	55.0	96.25	220

CALIBRATOR SERIAL DILUTIONS FOR DILUTED SAMPLE ANALYSIS ON THE KONELAB (This analyzer 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).

Accordingly, you should programme 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
<u>approx.</u> dilution factor of neat std.		0.14	0.28	0.56	1.12	2.24
A-I	mg/dl	32.1	64.1	128.2	256.5	513
B	mg/dl	30.8	61.6	123.2	246.4	493

CALIBRATOR SERIAL DILUTIONS FOR DILUTED SAMPLE ANALYSIS (for use 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 programme 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
<u>approx.</u> dilution factor of neat std.		0.14	0.28	0.56	1.12	2.24
A-I	mg/dl	32.1	64.1	128.2	256.5	513
B	mg/dl	30.8	61.6	123.2	246.4	493

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 programme the instrument with the following values:

	S1	S2	S3	S4	S5
Dilution	Saline	1+7	1+3	1+1	Neat
A-I (mg/dl)	0	28.625	57.25	114.5	229
B (mg/dl)	0	27.5	55.0	110	220

10 Nov '08