Apolipoproteins A1 & B Calibrators KIT

✓ ***REFERENCE***

5 calibrators KIT	ABREK-000	5 x 0.5 ml	2-8°C
Human biological fluid containing apolipoproteins A1 and B standardized from a secondary reference materiel related to IFCC (SP1– 01 and SP3-07) and certified by the World Health Organisation , sodium azide (< 1g/l)			
Lot #		19D16	
Expiry date		09/2020	
Control date		17/06/2019	
Quality control report #		DGM-QAC-REP-19067	
Document prepared and signed by		L.Ginneberge	

✓ ***SAMPLES AND REFERENCE VALUES***

See the corresponding reagents technical sheet.

✓ ***COMPOSITION***

APO A1&B calibrators are human biological fluids containing human apolipoproteins A1 & B at fixed values and sodium azide (<1g/l) as preservative.

✓ ***PRINCIPLE OF TEST***

The human APO A1 & B react upon a specific antibody for corresponding protein and the turbidity induced by the formation of immune complexes is recorded at appropriate wavelength. The turbidity measured is directly proportional to the APO A1 & B concentration of the calibrators which can be used for the quantitative determination of APO A1 & B in immunoturbidimetry.

✓ ***PRECAUTIONS***

For in vitro single diagnostic use. To be handled by entitled Personnel.
Products from human source were tested and found free from HBsAg and antibodies to HCV and HIV but this material should be treated just as carefully as potentially infective.
Products containing sodium azide have to be handled with care; avoid ingestion and contact with skin and mucous membranes. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

✓ ***ANALYTICAL PERFORMANCES***

See the corresponding reagents technical sheet.

✓ ***PREPARATION AND REAGENTS STABILITY***

The calibrators are ready for use; once opened, they are stable until expiry date if stored stoppered in appropriate temperature conditions and without any contamination (avoid pipetting and decantation).

✓ ***METHOD OF ANALYSIS AND CALCULATION***

See the corresponding reagents technical sheet.

✓ ***QUALITY CONTROL***

Accuracy and reproducibility: analytical performances can be checked with the internal quality control serum of the laboratory or with the Liquichek™ (BIO-RAD) Control sera (see the values range obtained with DiAgam reagents and indicated on the accompanying BIO-RAD sheet).
Calibration: calibration curve and stability of calibration curve can be validated with the DiAgam calibration control (ABCON-002).
In case of analytical performances modification, calibrate the method again and contact the manufacturer if modifications are subsisting.

✓ ***BIBLIOGRAPHY***

(1) Marcovina, S.M. et al. Standardization of Apolipoprotein B and A-I Measurements. Clin. Chem. 35/7, (1989) 1357-1361
(2) Marcovina, S.M. et al. International Federation of Clinical Chemistry Standardization Project for Measurements of Apolipoproteins A-I and B Clin. Chem. 37/10, (1991) 1676-1682
(3) Marcovina, S.M. et al. International Federation of Clinical Chemistry Standardization Project for Measurements of Apolipoproteins A-I and B. III. Comparability of Apolipoprotein A-I values by use of international reference material. Clin. Chem. 39, (1993) 773-781
(4) Marcovina, S.M. et al. International Federation of Clinical Chemistry Standardization Project for Measurements of Apolipoproteins A-I and B. IV. Comparability of Apolipoprotein B values by use of international reference material. Clin. Chem. 40/4, (1994) 586-592
(5) Dati, F. and Tate J. Reference Materials for the Standardization of the Apolipoproteins A-I and B, and Lipoprotein(a). eJIFCC vol 13 no 3: http:// www.ifcc.org/ejifcc/vol13no3/130301003.htm

CE

ABREKFTEN 19/06/2019 v02

	CAL 1		CAL 2		CAL 3		CAL 4		CAL 5	
	g/l		g/l		g/l		g/l		g/l	
	certified val.	*U**	certified val.	*U**	certified val.	*U**	certified val.	*U**	certified val.	*U**
APO A1	**0.32**	*0.02*	**0.62**	*0.03*	**1.20**	*0.06*	**1.85**	*0.09*	**2.29**	*0.12*
APO B	**0.40**	*0.02*	**0.74**	*0.04*	**1.38**	*0.07*	**2.19**	*0.11*	**2.80**	*0.14*

U: The certified uncertainty is the half-width of the 95 % confidence interval of the mean.*
Values assigned from a secondary reference materiel related to IFCC (SP1 - 01 and SP3 - 07).

DiAgam Avenue Louis Lepoutre 70 – 1050 BRUSSELS Belgium **mail@diagam.com** **Tel: +32 (0) 68 55 14 82 / Fax: +32 (0) 68 56 89 40**