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)			
Batch number :		**21J04**	
Expiry date :		**03/2023**	
Control date :		**10/02/22**	
Quality control report :		DGM-QAC-REP-**21231**	
Document prepared and signed by :		**Do Bach Mai**	

✓ ***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
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(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

ABREK 21J04 IFU EN v02 10/02/22

	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	**0,28**	*0,01*	**0,56**	*0,03*	**1,13**	*0,06*	**1,77**	*0,09*	**2,11**	*0,11*
APO B	**0,35**	*0,02*	**0,63**	*0,03*	**1,15**	*0,06*	**1,97**	*0,10*	**2,57**	*0,13*

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 **Tél: +32 (0) 68 55 14 82** **Fax: +32 (0) 68 56 89 40**
DISTRIBUTEUR: DiAgam France – 130 Boulevard de la Liberté- 59000 LILLE **Tél: +33 (0) 3 20 42 85 17** **Fax: +33 (0) 3 20 54 22 07**

Symbols

The following symbols may appear on the packaging and labelling :

LOT	*Batch code*	BUF	*Buffer*
	Use by	CAL	*Calibrator*
	Manufacturer	H	*High*
IVD	*In Vitro Diagnostics Medical Device*	M	*Medium*
	Temperature limitation (store at)	L	*Low*
REF	*Catalogue number*	4 LEV	*4 levels*
	Consult instructions for use	5 LEV	*5 levels*
REAG	*Reagent*	6 LEV	*6 levels*
KIT	*Kit*	CONTROL	*Control*
CONT	*Contents*	CE	*This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro*
Ab	*Antibody or Antiserum*		Track version changes

	DiAgam Belgium: Rue du Parc Industriel 40, 7822 Ghislenghien, Belgium
DiAgam Headquarters	*Avenue Louis Lepoutre 70, 1050 Bruxelles, Belgique*
Distributed by	*DiAgam France: Boulevard de la Liberté 130, 59000 Lille, France*