Lipoporotein (a) calibrators kit (Lp(a))

✓ ***REFERENCE***

Lp(a) calibrators KIT	LPREK-000	4 x 0.5 ml	2-8 °C
Human biological fluid containing Lp(a) standardized from a secondary preparation of human Lipoprotein(a), sodium azide (< 1g/l)			
Batch number :		**21J05**	
Expiry date :		**07/2022**	
Control date :		**22/10/21**	
Quality control report :		DGM-QAC-REP-**21230**	
Document prepared and signed by :		**Do Bach Mai**	

✓ ***SAMPLES AND REFERENCE VALUES***
See the corresponding reagents technical sheet.

✓ ***COMPOSITION***
The lipoprotein(a) calibrator is a human biological fluid containing human Lp(a) at fixed value and sodium azide (<1g/l) as preservative.

✓ ***PRINCIPLE OF TEST***
The human Lp(a) reacts upon a specific antibody for human Lp(a) and the turbidity induced by the formation of immune complexes is recorded at 340 nm. The turbidity measured is directly proportional to the Lp(a) concentration of the calibrator which can be used for the quantitative determination of Lp(a) 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, it is 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.
Calibration: calibration curve and stability of calibration curve can be validated with the DiAgam calibration control (**LPCON-002**).
Calibrate when the quality control results are outside acceptable range (contact the manufacturer if the deviations subsist), when the reagent lot number changes or when government regulations require.

✓ ***BIBLIOGRAPHY***
(1) Tate, J.R. et al. International Federation of Clinical Chemistry standardization project for the measurements of lipoprotein (a). Phase I. Evaluation of the analytical performance of lipoprotein (a) assay systems and commercial calibrators. Clin. Chem. 44:8, (1998) 1629-1640
(2) Kostner, G.M. et al. Preparation of a stable fresh frozen primary lipoprotein(a) (Lp(a)) standard. Journal of Lipid Research. 40, (1999) 2255-2263
(3) Marcovina, S.M. et al. Use of Reference Material Proposed by the International Federation of Clinical Chemistry and Laboratory Medicine to Evaluate Analytical Methods for the Determination of Plasma Lipoprotein(a). Clin. Chem. 46:12, (2000) 1956-1967

CE

LPREK 21J05 IFU EN v02 22/10/21

	CAL 1		CAL 2		CAL 3		CAL 4	
	mg/dl		mg/dl		mg/dl		mg/dl	
	certified val.	*U**	certified val.	*U**	certified val.	*U**	certified val.	*U**
Lp(a)	**11.55**	*0.58*	**19.22**	*0.96*	**40.95**	*2.05*	**84.00**	*4.20*

U : The certified uncertainty is the half-width of the 95% confidence interval of the mean.*
Values assigned from a secondary preparation of human Lipoprotein(a).

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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

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