Anti Streptolysin O (ASO) Calibrator KIT

✓ ***REFERENCE***

5 calibrators KIT	ASREK-000	5 x 1 ml	2-8 °C
Human serum ASO standardized from the reference SSI (1st International Standard for antistreptolysin O), sodium azide (0.075%)			
Batch number :		**22E16**	
Expiry date :		**10/2023**	
Control date :		**05/07/22**	
Quality control report :		DGM-QAC-REP-**22130**	
Document prepared and signed by:		**Do Bach Mai**	

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

✓ ***COMPOSITION***
Human serum ASO standardized from the reference SSI (1st International Standard for antistreptolysin O), sodium azide (0.075%).

✓ ***PRINCIPLE OF TEST***
The human serum sample reacts upon polystyrene latex particles coated with streptolysin O. In the presence of ASO, the particles agglutinate. This induces an increase in optical density at 600 nm, which is directly proportional to the ASO titre in the sample.

✓ ***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 calibrator is 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 or with the Liquichek™ (BIO-RAD) Control sera.
Calibration: calibration curve and stability of calibration curve can be validated with the DiAgam calibration control (**ASCON-002**).
In case of analytical performances modification, calibrate the method again and contact the manufacturer if modifications are subsisting.

✓ ***BIBLIOGRAPHY***
Spaun, J. et al., International standard for anti-streptolysin-O. Bull. WHO 24 (1961) 271-279.

CE

ASREK 22E16 IFU EN v01 05/07/22

	CAL 1		CAL 2		CAL 3		CAL 4		CAL 5	
	UI/ml		UI/ml		UI/ml		UI/ml		UI/ml	
	certified val.	*U**	certified val.	*U**	certified val.	*U**	certified val.	*U**	certified val.	*U**
ASO	**90.62**	*4.531*	**172.33**	*8.617*	**255.75**	*12.788*	**346.68**	*17.334*	**523.78**	*26.189*

U: The certified uncertainty is the half-width of the 95% confidence interval of the mean.*
Values assigned from the 1st International Standard for anti-streptolysin-O, human (code ASO). The material has been prepared and characterized by Statens Seruminstitut (SSI), Copenhagen, Denmark

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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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