Fibrinogen calibrator

✓ ***REFERENCE***

Fibrinogen calibrator	FIREM-001	1 x 1 ml	2-8 °C
Fibrinogen calibrator is a plasmatic biological fluid standardized from the 3rd international standard for fibrinogen plasma (NIBSC code 09/264), stabilizers			
Batch number :		**22C01**	
Expiry date :		**07/2024**	
Control date :		**21/04/22**	
Quality control report :		DGM-QAC-REP-**22083**	
Document prepared and signed by :		**L.Ginneberge**	

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

✓ ***COMPOSITION***
Fibrinogen calibrator is a plasmatic biological fluid containing human Fibrinogen at fixed value standardized from the 2nd international standard for fibrinogen plasma (NIBSC code 98/612). Fibrinogen calibrator was processed from human plasma collected with sodium citrate anticoagulant. Stabilizers are added before lyophilisation.

✓ ***PRINCIPLE OF TEST***
The human Fibrinogen reacts upon a specific antibody for human Fibrinogen and the turbidity induced by the formation of immune complexes is recorded at 340 nm. The turbidity measured is directly proportional to the Fibrinogen concentration of the calibrator which can be used for the quantitative determination of Fibrinogen 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 calibrator has to be stored in unopened vial at 2-8°C.The calibrator is lyophilized and has to be reconstituted before use with 1 ml of distilled water; swirl gently and let stand undisturbed for 15 minutes at room temperature. Do not invert vial or mix vigorously. Gently mix contents before each use. Once proper reconstituted, it is stable for 8 hours at 2-8°C in capped vial; the reconstituted appearance is straw to yellow and clear to hazy.

✓ ***METHOD OF ANALYSIS AND CALCULATION***
See the corresponding reagents technical sheet

✓ ***QUALITY CONTROL***
Accuracy and reproducibility: Accuracy and reproducibility: analytical performances can be checked with the internal quality control plasma of the laboratory.
Calibration: In case of analytical performances modification, calibrate the method again and contact the manufacturer if modifications are subsisting.

✓ ***BIBLIOGRAPHY***
WHO International Standard 3rd INTERNATIONAL STANDARD FIBRINOGEN PLASMA NIBSC code: 09/264
http://www.nibsc.ac.uk/documents/ifu/09-264.pdf

CE

FIREM 22C01 IFU EN v03 25/04/22

Fibrinogen	CAL	M
	mg/dl	
	292	

Values assigned from the 3rd international standard for fibrinogen plasma (NIBSC code 09/264)

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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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