

✓ **REFERENCE**

Fibrinogen control	FICON-001	1 ml	2-8°C
Fibrinogen control is a plasmatic biological fluid standardized from the 3 rd international standard for fibrinogen plasma (NIBSC code 09/264), stabilizers			
Lot #	19L03		
Expiry date	05/2021		
Control date	03/03/2020		
Quality control report #	DGM-QAC-REP-19182		
Document prepared and signed by	L.Ginneberge		

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

Fibrinogen control is a plasmatic biological fluid containing human. Fibrinogen control 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.

✓ **ANALYTICAL PERFORMANCES**

See the corresponding reagents technical sheet.

✓ **PREPARATION AND REAGENTS STABILITY**

The control has to be stored in unopened vial at 2-8°C. The control is lyophilized and has to be reconstituted before use with 1 ml of distilled water; swirl gently and let stand undisturbed for 30 minutes at room temperature. Do not invert vial or mix vigorously. Gently mix contents before each use. Once properly reconstituted, it is stable for 6 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>



FICONFTEN 03/03/2020 v03

Fibrinogen	CONTROL	
	mg/dl	
	Target	Range
	282	226 - 338

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