HYPHEN BioMed
A Company of Sysmex Group

HYPHEN BioMed
155 rue d'Eragny
95000 Neuville-sur-Oise
France

CERTIFICATE OF ANALYSIS

Product Description: BIOPHEN FVIII:C

Product Code: 221402

Lot No.: FB04059L

Expiration date: 2024-08-16

Components	Quantity	Lot	Expiration Date
R1: Human FX	2 vials	FB0405h89L	2024-10-21
R2: Activation reagent	2 vials	FB0405h99L	2024-10-27
R3: Substrate	2 vials	FB0405i19L	2024-08-19
R4: Buffer	4 vials	FB0405i29L	2024-08-16

Analytical Data	Specification	Result
Calibration curve: reactivity, linearity, slope and accuracy	Water-Bath (High Range) A405 (200%) ≥ 1.60 Delta A405 (100 ; 200%) ≥ 0.60 $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	2.422 1.015 PASS PASS
Calibration curve: reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) ≥ 0.80 Delta A405 (12.5; 25%) ≥ 0.30 $R^2 \geq 0.98$	1.308 0.627 PASS
Detection Threshold High Range	≤ 10%	< 5 %
Detection Threshold Low Range	≤ 2 %	< 1 %

Calibration Curve for information HIGH RANGE

Conc.	200%	100,0%	50%	25%	12.5%
OD WB	2.422	1.407	0.684	0.310	0.131
Conc.	200%	133%	100%	50%	20%
OD STAR	0.802	0.610	0.459	0.233	0.0081

	Acceptance Range	MV
NC	[91 - 111]	103
AC	[29 - 40]	36

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	25%	12.5%	6.25%	3.12%
OD WB	1.308	0.681	0.340	0.152
Conc.	25%	12.5%	6.25%	1.56%
OD STAR	1.193	0.708	0.357	0.083

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Date of Approval: 2022-06-07

Quality Control Manager: **S. LECOURT**