



HYPHEN BioMed  
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France

<b>CERTIFICATE OF ANALYSIS</b>	
<b>Product Description</b>	<b>BIOPHEN PLASMA CALIBRATOR</b>
<b>Product Code :</b>	<b>222101</b>
<b>Lot No. :</b>	<b>F2000232</b>
<b>Expiration date :</b>	<b>2022-08-23</b>

<b>Components</b>	<b>Quantity</b>	<b>Lot</b>	<b>Expiration Date</b>
Plasma Calibrator	12 vials	F201700232	2022-08-23

<b>Analytical Data</b>	<b>Specification</b>	<b>Result</b>
Fibrinogen (Activity)	> 2 g/L	2.72 g/L
Fibrinogen (Antigen)	> 2 g/L	2.79 g/L
LA ratio	≤ 1.2	< 1.2
Alpha 2 Anti plasmin	> 85 %	103%
Antithrombin (Activity)	> 85 %	102%
Antithrombin (Antigen)	> 85 %	102%
Factor II	> 80 %	103%
Factor V	> 80 %	106%
Factor VII	> 80 %	102%
Factor X	> 80 %	96%
Factor VII+ X	> 85 %	100%
Factor VIII	> 60 %	111%
Factor IX	> 60 %	105%
Factor XI	> 70 %	101%
Factor XII	> 70 %	114%
Factor XIII	> 70 %	88%
Free Protein S (Antigen)	70 - 140 %	119%
Plasminogen	> 80 %	113%
Protein C Chromogenic	> 85 %	107%
Protein C Clotting	> 70 %	107%
Protein S (Activity)	> 50 %	99%
von Willebrand Factor (Antigen)	> 60 %	109%

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

Date of Approval: 2020-06-09

Quality Control Manager: S. LECOURT



## BIOPHEN™ Plasma Calibrator

**REF** : 222101

**LOT** : F2000232

 : 23/08/2022

Parameters	Unit	Method	Target Value
Fibrinogen	g/L	CS - STAR / FIBRIPHEN™	2.72 g/L
		STAR / LIAPHEN™ Fibrinogen	2.79 g/L
Lupus Anticoagulant (LA)	Ratio	Stago DRVVT screen / Stago DRVVT confirm	≤ 1.20
α2 – Antiplasmin	%	CS / BIOPHEN® α2 – Antiplasmin (LRT)	103%
Antithrombin	%	CS- STAR / BIOPHEN™ Antithrombin	102%
	%	STAR / LIAPHEN AT	102%
Plasminogen	%	CS / BIOPHEN Plasminogen	113%
Protein C	%	CS - STAR / BIOPHEN™ Protein C (chromogenic)	107%
	%	CS - STAR / HEMOCLOT Protein C (clotting)	107%
Protein S	%	STAR / HEMOCLOT™ Protein S (clotting)	99%
Free Protein S	%	CS / LIAPHEN™ Free Protein S	119%
Factor II	%	STAR / Deficient Plasma Factor II	103%
Factor V	%	STAR / Deficient Plasma Factor V – HEMOCLOT Factor V Reagent	106%
Factor VII	%	STAR / Deficient Plasma Factor VII – HEMOCLOT Factor VII Reagent	102%
Factor VII+X	%	STAR / HEMOCLOT VII-X	100%
Factor VIII:C	%	STAR / Deficient Plasma Factor VIII :C – BIOPHEN FVIII :C	111%
Factor IX	%	STAR / Deficient Plasma Factor IX – BIOPHEN™ FIX	105%
Factor X	%	STAR / Deficient Plasma Factor X	96%
Factor XI	%	STAR / Deficient Plasma Factor XI	101%
Factor XII	%	STAR / Deficient Plasma Factor XII	114%
Factor XIII	%	CS / BIOPHEN™ Factor XIII	88%
von Willebrand Factor Antigen	%	CS – STAR / LIAPHEN™ vWF: Ag	109%