



A Company of Sysmex Group



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN FIXa CONTROL SET  
**Product Code :** 224601  
**Lot No. :** F1801406  
**Expiration date :** 2021-04-05

Components	Quantity	Lot	Expiration Date
C1	6 vials	F181401406	2021-04-05
C2	6 vials	F181801406	2021-04-05

Analytical Data	Specification	Result
Concentration	C1 : 5 -15 mIU/ml C2 : 15 - 25 mIU/ml	C1 = 6.8 mIU/mL C2 = 17.1 mIU/mL

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

Date of Approval : 2018-11-09

Quality Control Manager :

M.PEYRAFITTE

**BIOPHEN IXa CONTROL**

Two levels of FIXa controls for the quality control of FIXa measurements with chromogenic FIXa assay (Biophen FIXa)/

Deux niveaux de contrôles FIXa pour le contrôle de qualité des dosages de FIXa par méthode chromogène (Biophen FIXa)

**REF** 224601

For in vitro research use only / Pour recherche in vitro exclusivement

**LOT** F1801406

2021-04-05

**Factor IXa Concentration [C] in the controls /  
Concentration [C] en Factor IXa dans les contrôles**

<b>Control / Contrôle C1</b>	<b>LOT : F181401406</b>
Target value / Valeur cible :	<b>6.8 mIU/mL / mUI/mL</b>
Acceptance range / Intervalle d'acceptation :	<b>[ 5.4 - 8.2 ] mIU/mL / mUI/mL</b>

<b>Control / Contrôle C2</b>	<b>LOT : F181801406</b>
Target value / Valeur cible :	<b>17.1 mIU/mL / mUI/mL</b>
Acceptance range / Intervalle d'acceptation :	<b>[ 14.5 - 19.7 ] mIU/mL / mUI/mL</b>

Standardization / Standardisation : **Controls are qualified against 1st International Standard for FIXa (97/562).**

Approved Date / Date d'Approbation : 2018.11.09

Quality Control Manager / Responsable Contrôle Qualité : M.PEYRAFITTE

P.O.

