



A Company of Sysmex Group



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN UFH CONTROL C2  
**Product Code :** 223901  
**Lot No. :** F1801636-F1801637  
**Expiration date :** 2021-05-29

Components	Quantity	Lot	Expiration Date
C2	12 vials	F181401636-F181101637	2021-05-29

Analytical Data	Specification	Result
Concentration	C2 : 0.40 -0.60 IU/mL	0.50

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

Date of Approval : 2019-01-10      Quality Control Manager : S.LECOURT

**BIOPHEN UFH CONTROL C2**

Human plasma at one level of Unfractionated Heparin (UFH) for the quality control of Heparin measurements with anti-Xa methods/  
*Plasma humain à un niveau d'Héparine Non Fractionnée (HNF) pour le contrôle de qualité des dosages d'héparine par méthode anti-Xa*

**REF** 223901For in vitro diagnostic use only / *Pour diagnostic in vitro exclusivement***LOT**

F1801636



2021-05-29

Unfractionated Heparin Concentration [C] in the control /  
*Concentration [C] en Héparine Non Fractionnée dans le contrôle*

Control / <i>Contrôle C2</i>	LOT : <b>F181401636</b>
Target value / <i>Valeur cible</i> :	<b>0.50</b> IU/mL / <i>UI/mL</i>
Acceptance range / <i>Intervalle d'acceptation</i> :	<b>[ 0.35 – 0.65 ]</b> IU/mL / <i>UI/mL</i>

Standardization / *Standardisation* : **Control is calibrated against internal standard qualified against 6<sup>th</sup> IS for UFH 07/328 from NIBSC**Approved Date / *Date d'Approbation* : 2019-01-10Quality Control Manager / *Responsable Contrôle Qualité* : S.LECOURT