



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

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