



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. : F1900550
Expiration date : 2021-10-23

Components	Quantity	Lot	Expiration Date
C2	12 vials	F191500550	2021-10-23

Analytical Data	Specification	Result
Concentration	C2 : 0.40 -0.60 IU/mL	0.52 IU/mL

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

Date of Approval : 2019-05-27

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 223901

For in vitro diagnostic use only / *Pour diagnostic in vitro exclusivement*

LOT F1900550



2021-10-23

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

Control / <i>Contrôle C2</i>	LOT : F191500550
Target value / <i>Valeur cible</i> :	0.52 IU/mL / <i>UI/mL</i>
Acceptance range / <i>Intervalle d'acceptation</i> :	[0.37 – 0.67] IU/mL / <i>UI/mL</i>

Standardization / *Standardisation* : **Control is related to international standard UFH NIBSC 07/328.**

Approved Date / *Date d'Approbation* : 2019-05-27

Quality Control Manager / *Responsable Contrôle Qualité* : S.LECOURT

