



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN LMWH CONTROL PLASMA
Product Code : 223001
Lot No. : F1903174
Expiration date : 2022-04-05

Components	Quantity	Lot	Expiration Date
C3	6 vials	F192003024	2022-04-05
C4	6 vials	F192003025	2022-04-05

Analytical Data	Specification	Result
Concentration	C3 : 0.70 -0.90 IU/mL C4 : 1.05 -1.35 IU/mL	C3 : 0.80 IU/mL C4 : 1.25 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 : 2019-11-21

Quality Control Manager :

C.DUNOIS

P.O.



BIOPHEN LMWH CONTROL PLASMA

Human plasmas at two levels of Low Molecular Weight Heparin (LMWH) for the quality control of Heparin measurements with anti-Xa methods

REF 223001

For in vitro diagnostic use only

LOT F1903174  2022-04-05

Low Molecular Weight Heparin Concentration [C] in the controls

Control C3	LOT : F192003024
Target value :	0.80 IU/mL
Acceptance range :	[0.68 - 0.92] IU/mL

Control C4	LOT : F192003025
Target value :	1.25 IU/mL
Acceptance range :	[1.06 - 1.44] IU/mL

Standardization : Controls are calibrated against internal standard qualified against 3rd international standard for LMWH from NIBSC 11/176

Approved Date : 2019-11-21

Quality Control Manager : **C.DUNOIS**

