



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

CERTIFICATE OF ANALYSIS	
<b>Product Description :</b>	<b>ZYMUTEST FACTOR X</b>
<b>Product Code :</b>	<b>RK033A</b>
<b>Lot No. :</b>	<b>FA1735</b>
<b>Expiration date :</b>	<b>2023-10-30</b>

Components	Quantity	Lot	Expiration Date
Anti (h) Factor X pre-coated plate	12x8 wells	FA2109	2025-04-28
Factor X standard	3 vials	FA2134	2025-04-30
Factor X Control I	1 vial	FA2136	2025-04-30
Factor X Control II	1 vial	FA2135	2025-04-30
Anti-(h) Factor X HRP immunoconjugate	3 vials	FA2172	2025-05-08
Sample diluent	2x50 ml	F2000654	2023-10-30
Wash solution	1x50 ml	FA0257	2024-07-03
Conjugate diluent	1x25 ml	FA1119	2024-11-18
TMB	1x25 ml	210302D01	2025-03-30
Sulfuric Acid 0,45M	1x6 ml	FA0937	2024-10-14

Analytical Data	Specification	Result
Reactivity	A450 for 100 % $\geq$ 1.40	1.55
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	0.030
Detection threshold	$\leq$ 5%	< 1%

**Calibration Curve for information**

						Acceptance Range	MV	
Conc.	C	C/2	C/4	C/10	C/20	CI	[ 67 - 91 ]	74
OD	1.674	1.017	0.578	0.254	0.139	CII	[ 26 - 38 ]	30

MV = Measured value

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

Date of Approval : 2021-12-07

Quality Control Manager : S.LECOURT

