



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description: ZYMUTEST FACTOR VII
Product Code: RK036A
Lot No.: FB1038
Expiration date: 2024-12-13

Components	Quantity	Lot	Expiration Date
Anti (h) Factor VII pre-coated plate	12x8 wells	FB1039	2024-12-13
Factor VII standard	3 vials	FB1125	2024-12-23
Factor VII Control I	1 vial	FB1124	2025-12-18
Factor VII Control II	1 vial	FB1123	2025-12-18
Anti-(h) Factor VII HRP immunoconjugate	3 vials	FB1137	2024-12-28
Sample diluent	2x50 ml	FA1738	2025-03-10
Wash solution	1x50 ml	FB0867	2025-11-03
Conjugate diluent	1x25 ml	FA1521	2025-02-04
TMB	1x25 ml	210302D01	2025-03-30
Sulfuric Acid 0,45M	1x6 ml	FB0508	2025-09-01

Analytical Data	Specification	Result
Reactivity	A450 for 100 % \geq 1.00	1.591
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	< 0.05
Detection threshold	\leq 5%	< 5%

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

Date of Approval: 2022-07-28

Quality Control Manager: S. LECOURT

Accepted under waiver (NCI No 2014)