



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST FACTOR IX

Product Code : RK032A

Lot No. : FC2067

Expiration date : 2026-03-20

Components	Quantity	Lot	Expiration Date
Anti (h) Factor IX pre-coated plate	12x8 wells	FC2110	2026-03-20
Factor IX standard	3 vials	FC2068	2027-03-11
Factor IX Control I	1 vial	FC2070	2027-03-11
Factor IX Control II	1 vial	FC2069	2027-03-11
Anti-(h)-Factor IX HRP immunoconjugate	3 vials	FC2108	2026-03-23
Sample diluent	2x50 ml	FC1498	2026-12-01
Wash solution	1x50 ml	FC1080	2026-09-22
Conjugate diluent	1x25 ml	FC1584	2026-12-16
TMB	1x25 ml	221201D01	2026-12-31
Sulfuric Acid 0,45M	1x6 ml	FC1736	2027-01-04

Analytical Data	Specification	Result
Reactivity	A450 for 100 % ≥ 1.30	1.71
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	0.038
Detection threshold	$\leq 5\%$	$< 1\%$

Calibration Curve for information

Conc.	C	C/2	C/4	C/10	C/20
OD	1.872	1.322	0.848	0.412	0.244

MV = Measured value

	Acceptance Range	MV
CI	[67 - 91]	76
CII	[26 - 40]	32

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

Date of Approval : 2023-11-02

Quality Control Manager : S. LECOURT