



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST Fibrinogen

Product Code : RK024A

Lot No. : FC1159

Expiration date : 2026-01-31

Components	Quantity	Lot	Expiration Date
pre-coated plate	12x8 wells	FC2491	2026-05-29
Fibrinogen Standard	3 vials	FC2354(*)	2026-05-11
Fibrinogen Control I	1 vial	FC2356	2026-05-11
Fibrinogen Control II	1 vial	FC2358	2026-05-11
Fibrinogen HRP immunoconjugate	3 vials	FD0013	2026-06-22
B2F Sample diluent	2x50 ml	FC2360	2026-05-08
Wash solution	1x50 ml	FC1080	2026-09-22
B2F Conjugate diluent	1x25 ml	FC2361	2026-05-08
TMB	1x25 ml	220106D03	2026-01-31
Sulfuric Acid 0,45M	1x6 ml	FC2362	2027-05-03

Analytical Data	Specification	Result
Reactivity	A450 for 40 ng/ml \geq 1.45	1.75
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.150	0.017
Detection threshold	\leq 1 ng/ml	< 1 ng/mL

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

(*) NCI 2291 : Accepted underwaiver

Date of Approval : 2024-01-18

Quality Control Manager : S.LECOURT