



A Sysmex Group Company



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

CERTIFICATE OF ANALYSIS

Product Description: ZYMUTEST tPA Antigen

Product Code: RK011A

Lot No.: FC1621

Expiration date: 2025-12-27

Components	Quantity	Lot	Expiration Date
Anti-(h)-tPA pre-coated plate	12x8 wells	FC1622	2025-12-27
tPA standard 0 to 3	4 vials	STD 0 -> FC1680 STD 1-> FC1675 STD 2 -> FC1678 STD 3 -> FC1679	2026-12-31
Control I	1 vial	FC1676	2026-12-31
Control II	1 vial	FC1677	2026-12-31
Anti-(h)-tPA HRP immunoconjugate	3 vials	FC1731	2026-01-09
F-Sample diluent	2x50 ml	FC1248	2026-10-20
Wash solution	1x50 ml	FC1080	2026-09-22
Conjugate diluent	1x25 ml	FC1583	2026-12-16
TMB	1x25 ml	220106D03	2026-01-31
Sulfuric Acid 0,45M	1x6 ml	FC1735	2027-01-04

Analytical Data	Specification	Result
Reactivity	A450 for 19 ng/ml $\geq$ 1.40	1.55
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	PASS
Detection threshold	≤ 0.5 ng/ml	< 0.5 ng/ml

Calibration Curve for information

Conc.	0	8.6	16.6	20.6
OD	0.055	0.896	1.400	1.639

MV = Measured value

Acceptance Range			MV
CI	13	11.0-15.0	13.4
CII	3.6	2.9-4.3	3.9

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

Date of Approval: 2023-09-19

Quality Control Manager: S. LECOURT