



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.: FD2242

Expiration date: 2027-04-23

Components	Quantity	Lot	Expiration Date
Anti-(h)-tPA pre-coated plate	12x8 wells	FD2249	2027-04-23
tPA standard 0	1 vial	FD2442	2028-05-18
tPA standard 1	1 vial	FD2248	2028-04-20
tPA standard 2	1 vial	FD2245	2028-04-20
tPA standard 3	1 vial	FD2244	2028-04-20
Control I	1 vial	FD2247	2028-04-20
Control II	1 vial	FD2246	2028-04-20
Anti-(h)-tPA HRP immunoconjugate	3 vials	FD2390	2027-05-14
F-Sample diluent	2x50 ml	FD2397	2028-05-08
Wash solution	1x50 ml	FD0331	2027-07-26
Conjugate diluent	1x25 ml	FD2352	2028-05-01
TMB	1x25 ml	240508D01	2028-05-31
Sulfuric Acid 0,45M	1x6 ml	FD1506	2028-01-12

Analytical Data	Specification	Result
Reactivity	A450 for 19 ng/ml ≥ 1.40	1.96
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	0.011
Detection threshold	≤ 0.5 ng/ml	< 0.5 ng/mL

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

Date of Approval:

Quality Control Manager:

Quality Control Approval

02 JAN. 2025

S. LECOURT