



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

CERTIFICATE OF ANALYSIS**Product Description : ZYMUTEST DDimer****Product Code : RK023A****Lot No. : FD1294****Expiration date : 2026-12-18**

Components	Quantity	Lot	Expiration Date
Anti-(h) DDimer pre-coated plate	12x8 wells	FD1430	2027-01-08
DDimer standard	3 vials	FD1288	2026-12-18
Control I	1 vial	FD1290	2026-12-18
Control II	1 vial	FD1292	2026-12-18
Anti-(h)- DDimer HRP immunoconjugate	3 vials	FD1427	2027-01-11
Sample diluent	2x50 ml	FD0573	2027-08-30
Wash solution	1x50 ml	FD0322	2027-07-26
Conjugate diluent	1x25 ml	FD0391	2027-08-02
TMB	1x25 ml	221201D01R	2027-10-31
Sulfuric Acid 0,45M	1x6 ml	FD0462	2027-08-09

Analytical Data	Specification	Result
Reactivity	A450 for 185 ng/ml ≥ 1.40	1.84
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	0.008
Detection threshold	$\leq 2 \text{ ng/ml}$	$< 1 \text{ ng/ml}$

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

Date of Approval : **12 AOUT 2024**

Quality Control Manager :

Claire DUNOIS
Dir. Etudes Clin. & Val.