



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST DDimer

Product Code : RK023A

Lot No. : F1801321

Expiration date : 2020-12-31

Components	Quantity	Lot	Expiration Date
Anti-(h) DDimer pre-coated plate	12x8 wells	F1801413	2021-04-04
DDimer standard	3 vials	F1801353	2021-03-22
Control I	1 vial	F1801354	2021-03-22
Control II	1 vial	F1801355	2021-03-22
Anti-(h)- DDimer HRP immunoconjugate	3 vials	F1801425	2021-04-10
Sample diluent	2x50 ml	F1701561	2021-06-02
Wash solution	1x50 ml	F1800109	2021-07-13
Conjugate diluent	1x25 ml	F1700906	2021-01-27
TMB	1x25 ml	161208D01	2020-12-31
Sulfuric Acid 0,45M	1x6 ml	F1800049	2021-06-29

Analytical Data	Specification	Result
Reactivity	A450 for 185 ng/ml \geq 1.50	1.741
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls Measured Values within acceptance ranges
Blank	< 0.100	0.012
Detection threshold	\leq 2 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.

Date of Approval : 2018-11-06

Quality Control Manager :

A.M VISSAC



Zymutest DDimer / DDimère**REF** RK023A**Assay of DDimer by ELISA / Dosage ELISA du DDimère**

For in vitro use only / Utilisation in vitro exclusivement - For research use only / Uniquement à usage de recherche

LOT F1801321

2020-12-31

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1801353 Concentration : 200 ng/mL
Control / Contrôle CI LOT : F1801354 Target value / Valeur cible : 1762 ng/mL Acceptance range / Domaine d'acceptation : [1498 - 2026] ng/mL
Control / Contrôle CII LOT : F1801355 Target value / Valeur cible : 133 ng/mL Acceptance range / Domaine d'acceptation : < 400 ng/mL

(*) Standardization / Standardisation : **N/A**

Note: Curve fitting suitable for RK023A using Magellan software (Tecan ©) : second-degree polynomial (**), third-degree polynomial (**), 4 parameters marquardt, 5 parameters marquardt, cubic spline, akima, and point to point / Les modes d'interpolation adaptés pour RK023A sur le logiciel Magellan (Tecan ©) sont : polynôme de degré 2 (**), polynôme de degré 3 (**), 4 paramètres marquardt, 5 paramètres marquardt, spline cubique, akima, et point par point.

(**) Best fit suggested / Mode d'interpolation à favoriser

Approved Date / Date d'Approbation : 2018-11-06

Quality Control Manager / Responsable Contrôle Qualité : A.M VISSAC

