



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

**CERTIFICATE OF ANALYSIS**
**Product Description : ZYMUTEST DDimer**
**Product Code : RK023A**
**Lot No. : F1900945**
**Expiration date : 2022-01-24**

Components	Quantity	Lot	Expiration Date
Anti-(h) DDimer pre-coated plate	12x8 wells	F1901012	2022-02-11
DDimer standard	3 vials	F1900946	2022-01-24
Control I	1 vial	F1900947	2022-01-24
Control II	1 vial	F1900948	2022-01-24
Anti-(h)- DDimer HRP immunoconjugate	3 vials	F1901013	2022-02-14
Sample diluent	2x50 ml	F1900572	2022-10-11
Wash solution	1x50 ml	F1900596	2022-10-25
Conjugate diluent	1x25 ml	F1900006	2022-06-21
TMB	1x25 ml	190405D01	2023-04-30
Sulfuric Acid 0,45M	1x6 ml	F1900172	2022-07-19

Analytical Data	Specification	Result
Reactivity	A450 for 185 ng/ml $\geq$ 1.50	1.63
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls in range
Blank	< 0.100	0.003
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 : 2019-09-18

Quality Control Manager : **S. LECOURT**

**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** F1900945

2022-01-24

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : <b>F1900946</b> Concentration : <b>198 ng/mL</b>
Control / Contrôle CI LOT : <b>F1900947</b> Target value / Valeur cible : <b>1917 ng/mL</b> Acceptance range / Domaine d'acceptation : [ <b>1629 – 2205</b> ] ng/mL
Control / Contrôle CII LOT : <b>F1900948</b> Target value / Valeur cible : <b>&lt; 400 ng/mL</b> Acceptance range / Domaine d'acceptation : <b>&lt; 400 ng/mL</b>

(\*) 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 : 2019-09-18

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT