



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST vWF: CBA

Product Code : RK038A

Lot No. : F1801572

Expiration date : 2020-12-31

Components	Quantity	Lot	Expiration Date
Collagen pre-coated plate	12x8 wells	F1801562	2022-05-09
vWF standard	3 vials	F1801621	2022-05-16
vWF Control I	1 vial	F1800881	2021-11-15
vWF Control II	1 vial	F1701242	2021-04-05
Anti-(h)- vWF HRP immunoconjugate	3 vials	F1801593	2022-05-19
Sample diluent	2x50 ml	F1801411	2022-03-28
Wash solution	1x50 ml	F1800925	2021-11-22
Conjugate diluent	1x25 ml	F1700906	2021-01-27
TMB	1x25 ml	161208D01	2020-12-31
Sulfuric Acid 0,45M	1x6 ml	F1700902	2021-01-20

Analytical Data	Specification	Result
Reactivity	A450 for 100 % \geq 1.00	1.67
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls in compliance
Blank	< 0.100	0.018
Detection threshold	\leq 5%	< 2%

Calibration Curve for information

Conc.	C	C/2	C/4	C/10	C/20
OD	2.202	1.337	0.806	0.347	0.156

	Acceptance Range	MV
CI	[72 - 98]	85
CII	[44 - 66]	55

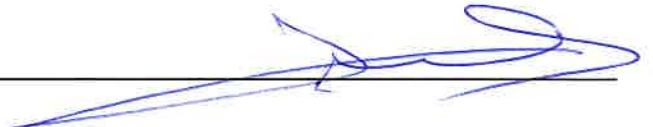
MV = Measured value

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

Date of Approval : 2018-12-13

Quality Control Manager :

S.LECOURT





Zymutest vWF: CBA

REF RK038A

Assay of Von Willebrand Factor Collagen Binding Activity by ELISA /

Dosage Elisa de l'activité de liaison au collagène du Facteur von Willebrand

For in vitro diagnostic use only / Usage diagnostic *in vitro* exclusivement

LOT F1801572



2020-12-31

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1801621 Concentration : 146 %
Control / Contrôle CI LOT : F1800881 Target value / Valeur cible : 85 % Acceptance range / Domaine d'acceptation : [72 - 98] %
Control / Contrôle CII LOT : F1701242 Target value / Valeur cible : 55 % Acceptance range / Domaine d'acceptation : [44 - 66] %

(*) Standardization / Standardisation : **Calibrator and controls are calibrated against internal standard related to international standard from NIBSC 07/316.**

Note: Curve fitting suitable for RK038A using Magellan software (Tecan ©) : second-degree polynomial (**), third-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt, akima, and point to point / *Les modes d'interpolation adaptés pour RK038A sur le logiciel Magellan (Tecan ©) sont : polynôme de degré 2 (**), polynôme de degré 3 (**), 4 paramètres, 4 paramètres marquardt, 5 paramètres marquardt, akima, et point par point.*

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

Approved Date / Date d'Approbation : 2018-12-13

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT