



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST vWF: CBA

Product Code : RK038A

Lot No. : F1800839

Expiration date : 2020-12-03

Components	Quantity	Lot	Expiration Date
Collagen pre-coated plate	12x8 wells	F1800870	2021-11-10
vWF standard	3 vials	F1700699	2020-12-03
vWF Control I	1 vial	F1800881	2021-11-15
vWF Control II	1 vial	F1800882	2021-11-15
Anti-(h)- vWF HRP immunoconjugate	3 vials	F1800956	2021-12-02
Sample diluent	2x50 ml	F1800266	2021-08-18
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	2.065
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls in acceptance range
Blank	< 0.100	0.016
Detection threshold	\leq 5%	< 0.1%

Calibration Curve for information

Conc.	C	C/2	C/4	C/10	C/20
OD	2.288	1.524	0.918	0.417	0.231

	Acceptance Range	MV
CI	[72 - 98]	87
CII	[38 - 56]	50

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 : 2018-07-06

Quality Control Manager : A.M VISSAC



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 F1800839



2020-12-03

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1700699 Concentration : 127 %
Control / Contrôle CI LOT : F1800881 Target value / Valeur cible : 85 % Acceptance range / Domaine d'acceptation : [72 - 98] %
Control / Contrôle CII LOT : F1800882 Target value / Valeur cible : 47 % Acceptance range / Domaine d'acceptation : [38 - 56] %

(*) 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 : 2018-07-06

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