

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST vWF: CBA

Product Code : RK038A

Lot No. : F1903206

Expiration date : 2022-12-06

Components	Quantity	Lot	Expiration Date
Collagen pre-coated plate	12x8 wells	F1903221	2023-05-16
vWF standard	3 vials	F1901028	2023-02-23
vWF Control I	1 vial	F1901030	2023-02-23
vWF Control II	1 vial	F1901031	2023-02-23
Anti-(h)- vWF HRP immunoconjugate	3 vials	F1903241	2023-05-25
Sample diluent	2x50 ml	F1901067	2023-02-21
Wash solution	1x50 ml	F1900767	2022-12-06
Conjugate diluent	1x25 ml	F1900898	2022-12-27
TMB	1x25 ml	190705D01	2023-07-30
Sulfuric Acid 0,45M	1x6 ml	F1903262	2023-05-29

Analytical Data	Specification	Result
Reactivity	A450 for 100 % \geq 1.00	2.04
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls Measured Values within acceptance ranges
Blank	< 0.100	0.008
Detection threshold	\leq 5%	< 1%

Calibration Curve for information

Conc.	C	C/2	C/4	C/10	C/20
OD	2.30	1.58	0.96	0.43	0.24

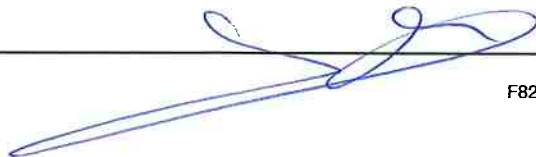
	Acceptance Range	MV
CI	[82 - 110]	94
CII	[41 - 61]	49

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: 2019-12-23

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** F1903206

2022-12-06

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1901028 Concentration : 128 %
Control / Contrôle CI LOT : F1901030 Target value / Valeur cible : 96 % Acceptance range / Domaine d'acceptation : [82 - 110] %
Control / Contrôle CII LOT : F1901031 Target value / Valeur cible : 51 % Acceptance range / Domaine d'acceptation : [41 - 61] %

(*) 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 : 2019-12-23

Quality Control Manager / Responsable Contrôle Qualité : **S. LECOURT**