



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

## CERTIFICATE OF ANALYSIS

**Product Description : ZYMUTEST vWF: CBA**

**Product Code : RK038A**

**Lot No. : F1901020**

**Expiration date : 2021-11-15**

Components	Quantity	Lot	Expiration Date
Collagen pre-coated plate	12x8 wells	F1901032	2023-02-13
vWF standard	3 vials	F1901028	2023-02-23
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	F1901105	2023-02-27
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	190405D01	2023-04-30
Sulfuric Acid 0,45M	1x6 ml	F1900840	2023-12-23

Analytical Data	Specification	Result
Reactivity	A450 for 100 % $\geq$ 1.00	1.78
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls Measured Values within acceptance ranges
Blank	$<$ 0.100	0.017
Detection threshold	$\leq$ 5%	$<$ 2%

### Calibration Curve for information

Conc.	C	C/2	C/4	C/10	C/20
OD	2.019	1.343	0.789	0.346	0.184

	Acceptance Range	MV
CI	[ 72 - 98 ]	86
CII	[ 38 - 56 ]	43

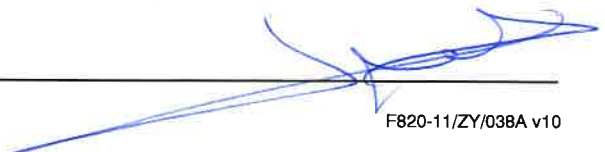
MV = Measured value

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

Date of Approval : 2019-10-02

Quality Control Manager :

**S. LECOURT**



F820-11/ZY/038A v10

## 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** F1901020



2021-11-15

<u>Values assigned / Valeurs cibles (*)</u>
<b>Calibrator / Calibrateur</b> LOT : <b>F1901028</b> Concentration : <b>128 %</b>
<b>Control / Contrôle CI</b> LOT : <b>F1800881</b> Target value / Valeur cible : <b>85 %</b> Acceptance range / Domaine d'acceptation : <b>[ 72 - 98 ] %</b>
<b>Control / Contrôle CII</b> LOT : <b>F1800882</b> Target value / Valeur cible : <b>47 %</b> Acceptance range / Domaine d'acceptation : <b>[ 38 - 56 ] %</b>

(\*) 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 : 2019-10-02

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT

