



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST vWF

Product Code : RK030A

Lot No. : F1701266

Expiration date : 2020-12-03

Components	Quantity	Lot	Expiration Date
Anti (h) vWF pre-coated plate	12x8 wells	F1701442	2021-05-12
vWF standard	3 vials	F1700699	2020-12-03
vWF Control I	1 vial	F1701241	2021-04-05
vWF Control II	1 vial	F1701242	2021-04-05
Anti-(h)-vWF HRP immunoconjugate	3 vials	F1701538	2021-05-27
Sample diluent	2x50 ml	F1700958	2021-02-09
Wash solution	1x50 ml	F1701244	2021-04-06
Conjugate diluent	1x25 ml	F1700772	2020-12-23
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 % ≥ 1.40	PASS
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	PASS
Detection threshold	$\leq 5\%$	$< 1\%$

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

Date of Approval : 2018-01-16

Quality Control Manager :

S.LECOURT



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ENGLISH / FRANÇAIS



Zymutest vWF

REF RK030A

Assay of Von Willebrand Factor by ELISA /

Dosage Elisa du facteur von Willebrand

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

LOT F1701266



2020-12-03

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1700699 Concentration : 127 %
Control / Contrôle CI LOT : F1701241 Target value / Valeur cible : 79 % Acceptance range / Domaine d'acceptation : [67 - 91] %
Control / Contrôle CII LOT : F1701242 Target value / Valeur cible : 48 % Acceptance range / Domaine d'acceptation : [38 - 58] %

(*) Standardization / *Standardisation* : calibrator and controls are qualified against internal standard itself indirectly qualified against the 6th IS factor VIII/vWF Plasma (07/316)

Note: Curve fitting suitable for RK030A using Magellan software (Tecan ®) : second-degree polynomial (**), third-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt, cubic spline, akima, and point to point / *Les modes d'interpolation adaptés pour RK030A sur le logiciel Magellan (Tecan ®) sont : polynôme de degré 2 (**), polynôme de degré 3 (**), 4 paramètres, 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* : 2018-01-16

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