

HYPHEN BioMed
155 rue d'Eragny
95000 NEUVILLE SUR OISE
FRANCE

Tel:+33.1.34.40.65.10
Fax:+33.1.34.48.72.36
www.hyphen-biomed.com

CERTIFICATE OF ANALYSIS

**ZYMUTEST
VWF:CBA ELISA kit**

#RK038A

Lot : F1601196

Expiration date : 2019-08-19



ANALYSIS CERTIFICATE

VWF:CBA ELISA kit

Lot : F1601196

QC Release : 2017-01-27

Expiration date : 2019-08-19

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Collagen pre-coated plate	12x8 wells	30	F1700065	2020-06-29
VWF calibrator	3 vials	42	F1600326	2019-08-19
Anti-(h)-VWF-HRP immunoconjugate	3 vials	42	F1700074	2020-07-03
Sample diluent	2x50	42	F1601300	2020-06-15
Wash solution	1x50	42	F1600895	2020-02-17
Conjugate diluent	1x25	42	F1600708	2019-12-11
VWF Control I	1 vial	42	F1600299	2019-08-19
VWFControl II	1 vial	42	F1600300	2019-08-19
TMB substrate	1x25		150915D02	2019-09-30
Sulfuric Acid 0,45M	1x6	42	F1600893	2020-02-19

805

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Analytical data	Specifications
1. <u>Reactivity</u>	
A450 for calibrator 100% : 2,00	≥ 1,00

2. <u>Calibrator Plasma</u>	
Concentration 138 %	120 to 160 %
CV 2,1 %	≤ 10 %

3. <u>Blank value</u>	
A450 for sample diluent : 0,024	< 0.100
SD : 0,010	< 0.015

4. <u>Calibration curve</u>																																				
Curve Fitting : polynomial 2																																				
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Conc.</th> <th style="width: 15%;">OD</th> <th style="width: 15%;">SD</th> <th style="width: 15%;">CV (%)</th> <th style="width: 40%;">CV (%)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C</td> <td style="text-align: center;">2,233</td> <td style="text-align: center;">0,184</td> <td style="text-align: center;">8,2</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/2</td> <td style="text-align: center;">1,573</td> <td style="text-align: center;">0,09</td> <td style="text-align: center;">5,7</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/4</td> <td style="text-align: center;">0,974</td> <td style="text-align: center;">0,05</td> <td style="text-align: center;">5,1</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/10</td> <td style="text-align: center;">0,460</td> <td style="text-align: center;">0,02</td> <td style="text-align: center;">5,1</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/20</td> <td style="text-align: center;">0,245</td> <td style="text-align: center;">0,01</td> <td style="text-align: center;">3,9</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">0,024</td> <td style="text-align: center;">0,010</td> <td style="text-align: center;">/</td> <td style="text-align: center;"><10</td> </tr> </tbody> </table>	Conc.	OD	SD	CV (%)	CV (%)	C	2,233	0,184	8,2	<10	C/2	1,573	0,09	5,7	<10	C/4	0,974	0,05	5,1	<10	C/10	0,460	0,02	5,1	<10	C/20	0,245	0,01	3,9	<10	0	0,024	0,010	/	<10	
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5. <u>Detection threshold</u>	Concentration %	
	<1	≤ 5%

6. <u>Controls</u>		
	Target value %	Measured value %
Control I	88	82
Control II	59	56
		Acceptance range
		75 to 101
		47 to 71

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
Date : 2017-01-27	QC 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 F1601196



2019-08-19

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1600326 Concentration : 138 %
Control / Contrôle CI LOT : F1600299 Target value / Valeur cible : 88 % Acceptance range / Domaine d'acceptation : [75 - 101] %
Control / Contrôle CII LOT : F1600300 Target value / Valeur cible : 59 % Acceptance range / Domaine d'acceptation : [47 - 71] %

(*) Standardization / Standardisation : Calibrator and controls are qualified against internal standard related to 6th is Factor VIII/vWf Plasma (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 : 2017-01-27

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT