

HYPHEN BioMed
ZAC Neuville Université
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
Factor XIII ELISA kit**

#RK034A

Lot : F1500109

Expiration date : 2018-06-17

SK

ANALYSIS CERTIFICATE

Factor XIII ELISA kit

Lot : F1500109

QC release : 12/02/2016

Expiration date : 2018-06-17

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) FXIII pre-coated plate	12x8 wells	42	F1500100	2019-06-03
Plasma FXIII Calibrator	3 vials	42	F1500116	2019-06-17
Anti-(h)-FXIII-HRP immunoconjugate	3 vials	42	F1500117	2019-07-01
Sample diluent	2x50	30	151117E	2019-05
Wash solution	1x50	42	151026C	2019-04
Conjugate diluent	1x25	42	150331E	2018-09
Plasma FXIII Control I	1 vial	42	141217D	2018-06
Plasma FXIII Control II	1 vial	42	141217E	2018-06
TMB substrate	1x25		150914	2019-05
Sulfuric Acid 0,45M	1x6	42	151019B	2019-04

ANALYSIS CERTIFICATE

Factor XIII ELISA kit

Lot : F1500109

QC release : 12/02/2016

Expiration date : 2018-06-17

	Analytical data	Specifications																																										
1.	<u>Reactivity</u> A450 for calibrator at 100% : 1,690	≥ 1,00																																										
2.	<u>Calibrator Plasma</u> Concentration 140 % CV 3,7 %	≥ 100 % ≤ 10 %																																										
3.	<u>Blank value</u> A450 for sample diluent : 0,092 SD : 0,011	< 0.150 < 0.015																																										
4.	<u>Calibration curve</u> Curve Fitting : Polynom 3 <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: 15%;">N ≥10</th> <th style="width: 15%;">CV (%)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C</td> <td style="text-align: center;">1,924</td> <td style="text-align: center;">0,060</td> <td style="text-align: center;">3,1</td> <td style="text-align: center;">12</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/2</td> <td style="text-align: center;">1,471</td> <td style="text-align: center;">0,075</td> <td style="text-align: center;">5,1</td> <td style="text-align: center;">12</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/4</td> <td style="text-align: center;">0,988</td> <td style="text-align: center;">0,041</td> <td style="text-align: center;">4,2</td> <td style="text-align: center;">12</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/10</td> <td style="text-align: center;">0,518</td> <td style="text-align: center;">0,020</td> <td style="text-align: center;">3,8</td> <td style="text-align: center;">12</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">C/20</td> <td style="text-align: center;">0,311</td> <td style="text-align: center;">0,014</td> <td style="text-align: center;">4,4</td> <td style="text-align: center;">12</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">0,092</td> <td style="text-align: center;">0,011</td> <td style="text-align: center;">/</td> <td style="text-align: center;">12</td> <td style="text-align: center;"><10</td> </tr> </tbody> </table>	Conc.	OD	SD	CV (%)	N ≥10	CV (%)	C	1,924	0,060	3,1	12	<10	C/2	1,471	0,075	5,1	12	<10	C/4	0,988	0,041	4,2	12	<10	C/10	0,518	0,020	3,8	12	<10	C/20	0,311	0,014	4,4	12	<10	0	0,092	0,011	/	12	<10	
Conc.	OD	SD	CV (%)	N ≥10	CV (%)																																							
C	1,924	0,060	3,1	12	<10																																							
C/2	1,471	0,075	5,1	12	<10																																							
C/4	0,988	0,041	4,2	12	<10																																							
C/10	0,518	0,020	3,8	12	<10																																							
C/20	0,311	0,014	4,4	12	<10																																							
0	0,092	0,011	/	12	<10																																							
5.	<u>Detection threshold</u> Concentration % < 1 %	≤ 10%																																										
6.	<u>Controls</u> Target value % Control I 107 Control II 47	Measured value % 119 46	Acceptance range 91 to 123 % 38 to 56 %																																									
7.	<u>Performances</u> Measured value Normal Plasmas N = 20 91 % FXIII deficient plasma < 1 %	> 60% ≤ 10%																																										

<u>Comments :</u>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
-------------------	---

Date : 12/02/2016

QC Manager : S. LECOURT



Zymutest Factor XIII-A / Facteur XIII-A

REF RK034A

Factor XIII - A / Facteur XII - A

For in vitro use only / Utilisation in vitro exclusivement - For research use only / Uniquement à usage de recherche

LOT F1500109

 2018-06-17

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1500116 Concentration : 140 %
Control / Contrôle CI LOT : 141217D Target value / Valeur cible : 107 % Acceptance range / Domaine d'acceptation : [91-123] %
Control / Contrôle CII LOT : 141217E Target value / Valeur cible : 47 % Acceptance range / Domaine d'acceptation : [38-56] %

(*) Standardization / Standardisation: Calibrator and controls are qualified against internal standard qualified against international standard from NIBSC code 02/206

Note: Curve fitting suitable for RK034A using Magellan software (Tecan ®) :third-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt / Les modes d'interpolation adaptés pour RK034A sur le logiciel Magellan (Tecan ®) sont : polynôme de degré 3 (**), 4 paramètres, 4 paramètres marquardt, 5 paramètres marquardt.

(**) Best fit suggested / Mode d'interpolation à favoriser

Approved Date / Date d'Approbation : 12/02/2016

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT