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CERTIFICATE OF ANALYSIS

**ZYMUTEST
Protein Z ELISA kit**

#RK031A

Lot : F1700421

Expiration date : 2019-10-12

905

ANALYSIS CERTIFICATE

Protein Z ELISA kit

Lot : F1700421

QC release : 2017-06-22

Expiration date : 2019-10-12

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) PZ pre-coated plate	12x8 wells	30	F1700444	2019-10-12
Protein Z Calibrator	3 vials	30	F1700500	2019-10-21
Anti-(h)-PZ-HRP immunoconjugate	3 vials	30	F1700523	2019-10-29
Sample diluent	2x50	30	F1700520	2020-10-21
Wash solution	1x50	42	F1700646	2020-11-17
Conjugate diluent	1x25	42	F1601097	2020-04-08
PZ Control I	1 vial	30	F1700501	2019-10-21
PZ Control II	1 vial	30	F1700502	2019-10-21
TMB substrate	1x25		160816D01	2020-08-30
Sulfuric Acid 0,45M	1x6	42	F1700445	2020-10-06

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Analytical data	Specifications																																										
1. <u>Reactivity</u>																																											
A450 for standard 80 ng/ml: 1,672	≥ 1.50																																										
2. <u>Plasma Standard</u>																																											
Concentration 98 ng/ml	90-110 ng/ml																																										
CV 6,2 %	≤ 10 %																																										
3. <u>Blank value</u>																																											
A450 for sample diluent : 0,010	< 0.100																																										
SD : 0,004	< 0.015																																										
4. <u>Calibration curve</u>																																											
Curve Fitting : Polynomial degree 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: 15%;">N</th> <th style="width: 15%;">CV (%)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">98 ng/ml</td> <td style="text-align: center;">1,825</td> <td style="text-align: center;">0,05</td> <td style="text-align: center;">2,6</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">49 ng/ml</td> <td style="text-align: center;">1,212</td> <td style="text-align: center;">0,05</td> <td style="text-align: center;">3,8</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">24,5 ng/ml</td> <td style="text-align: center;">0,694</td> <td style="text-align: center;">0,03</td> <td style="text-align: center;">4,5</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">9,8 ng/ml</td> <td style="text-align: center;">0,282</td> <td style="text-align: center;">0,01</td> <td style="text-align: center;">5,1</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">4,9 ng/ml</td> <td style="text-align: center;">0,147</td> <td style="text-align: center;">0,005</td> <td style="text-align: center;">3,2</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;"><10</td> </tr> <tr> <td style="text-align: center;">0 ng/ml</td> <td style="text-align: center;">0,010</td> <td style="text-align: center;">0,004</td> <td style="text-align: center;">/</td> <td style="text-align: center;">N = 10</td> <td></td> </tr> </tbody> </table>	Conc.	OD	SD	CV (%)	N	CV (%)	98 ng/ml	1,825	0,05	2,6	N = 10	<10	49 ng/ml	1,212	0,05	3,8	N = 10	<10	24,5 ng/ml	0,694	0,03	4,5	N = 10	<10	9,8 ng/ml	0,282	0,01	5,1	N = 10	<10	4,9 ng/ml	0,147	0,005	3,2	N = 10	<10	0 ng/ml	0,010	0,004	/	N = 10		
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5. <u>Detection threshold</u>																																											
Concentration <0,10 µg/mL	≤ 0.25 µg/ml																																										
6. <u>Controls</u>																																											
	Target value ng/ml	Measured value ng/ml	Acceptancy range																																								
Control I	3400	3627	2890 to 3910 ng/ml																																								
Control II	1161	1179	929 to 1393 ng/ml																																								
7. <u>Performances</u>		Measured value																																									
Normal Plasmas	N = 12	2,6	1 to 4 µg/ml																																								
PZ deficient plasma		<0,10	≤0.15 µg/ml																																								

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-06-22

QC Manager :



S. LECOURT



Zymutest Protein Z / Protéine Z

REF RK031A

Assay of Protein Z by ELISA / Dosage ELISA de la Protéine Z

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

LOT F1700421



2019-10-12

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1700500 Concentration : 98 ng/mL
Control / Contrôle CI LOT : F1700501 Target value / Valeur cible : 3400 ng/mL Acceptance range / Domaine d'acceptation : [2890-3910] ng/mL
Control / Contrôle CII LOT : F1700502 Target value / Valeur cible : 1161 ng/mL Acceptance range / Domaine d'acceptation : [929-1393] ng/mL

(*) Standardization / Standardisation : NA

Note: Curve fitting suitable for RK031A 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 RK031A 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 : 2017-06-22

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT