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CERTIFICATE OF ANALYSIS

**ZYMUTEST
Protein Z ELISA kit**

#RK031A

Lot : 150219D

Expiration date : 2017-02

ANALYSIS CERTIFICATE

Protein Z ELISA kit

Lot : 150219D

QC release : 04/03/2015

Expiration date : 2017-02

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) PZ pre-coated plate	12x8 wells	30	150209F	2017-08
Protein Z Calibrator	3 vials	30	140807D	2017-02
Anti-(h)-PZ-HRP immunoconjugate	3 vials	30	150212A	2017-08
Sample diluent	2x50	30	140514A	2017-11
Wash solution	1x50	42	141103K	2018-05
Conjugate diluent	1x25	42	140929I	2018-03
PZ Control I	1 vial	30	140807E	2017-02
PZ Control II	1 vial	30	140807F	2017-02
TMB substrate	1x25		140817	2018-08
Sulfuric Acid 0,45M	1x6	42	141104C	2018-05

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Analytical data				Specifications	
1. <u>Reactivity</u>					
A450 for standard :		1,893		> 1.60	
2. <u>Plasma Standard</u>					
Concentration		101 ng/ml		80-120 ng/ml	
CV		3,8 %		≤ 10 %	
3. <u>Blank value</u>					
A450 for sample diluent :		0,024		< 0.100	
SD :		0,014		< 0.015	
4. <u>Calibration curve</u>					
Conc.	OD	SD	CV (%)	N	CV (%)
101 ng/ml	1,893	0,05	2,7	N = 10	<10
50,5 ng/ml	1,251	0,04	3,2	N = 10	<10
25,25 ng/ml	0,742	0,03	4,3	N = 10	<10
10,1 ng/ml	0,350	0,01	3,0	N = 10	<10
5,05 ng/ml	0,186	0,01	6,2	N = 10	<10
0 ng/ml	0,024	0,01	/	N = 10	<10
5. <u>Detection limit</u>					
Sensitivity		Concentration <0,1		≤ 0.25 µg/ml	
6. <u>Controls</u>					
	Target value ng/ml	Measured value ng/ml		Acceptancy range	
Control I	3097	3293		2632 to 3562 ng/ml	
Control II	1251	1182		1001 to 1501 ng/ml	
7. <u>Performances</u>					
	N = 12	Measured value		Acceptancy range	
Normal Plasmas		2,30		1 to 4 µg/ml	
PZ deficient plasma		<0,10		≤0.15 µg/ml	

<u>Comments :</u>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 04/03/15

QC Manager :

AM.VISSAC

DIAPHARMA Protein Z

DPCR031A

Assay of Protein Z by ELISA

For in vitro research use only

Lot : 150219D - Exp. : 2017-02

Standard Plasma Lot : 140807D

PZ concentration: 101 ng/ml

Control I Lot : 140807E

PZ concentration: 3097 ng/ml

Acceptance range: 2632 – 3562 ng/ml

Control II Lot : 140807F

PZ concentration: 1251 ng/ml

Acceptance range: 1001 – 1501 ng/ml

Handwritten signature and date:
19.06.15