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CERTIFICATE OF ANALYSIS

**ZYMUTEST
Protein Z ELISA kit**

#RK031A

Lot : 140429M

Expiration date : 2016-03



ANALYSIS CERTIFICATE

Protein Z ELISA kit

Lot : 140429M

QC release : 29/04/2014

Expiration date : 2016-03

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) PZ pre-coated plate	12x8 wells	30	140422A	2016-10
Protein Z Calibrator	3 vials	30	130910D	2016-03
Anti-(h)-PZ-HRP immunoconjugate	3 vials	30	140425C	2016-10
Sample diluent	2x50	30	140107C	2017-07
Wash solution	1x50	42	131008C	2017-04
Conjugate diluent	1x25	42	140205A	2017-08
PZ Control I	1 vial	30	130910E	2016-03
PZ Control II	1 vial	30	130910F	2016-03
TMB substrate	1x25		140106	2018-01
Sulfuric Acid 0,45M	1x6	42	140129A	2017-07

760

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Analytical data		Specifications
1. <u>Reactivity</u>		
A450 for standard :	2.19	> 1.60

2. <u>Plasma Standard</u>		
Concentration	97 ng/ml	80-120 ng/ml
CV	3.9 %	≤ 10 %

3. <u>Blank value</u>		
A450 for sample diluent :	0.019	< 0.100
SD :	0.006	< 0.015

4. <u>Calibration curve</u>						
Conc.	OD	SD	CV (%)	N	CV (%)	
97 ng/ml	2.19	0.04	1.8	N = 10	<10	
48.5 ng/ml	1.60	0.05	3.1	N = 10	<10	
24.3 ng/ml	1.00	0.02	1.9	N = 10	<10	
9.7 ng/ml	0.44	0.01	2.0	N = 10	<10	
4.9 ng/ml	0.26	0.02	8.4	N = 10	<10	
0 ng/ml	0.019	0.006	/	N = 10	<10	

5. <u>Detection limit</u>		Concentration
Sensitivity	<0.20	≤ 0.25 µg/ml

6. <u>Controls</u>	Target value ng/ml	Measured value ng/ml	Acceptancy range
Control I	2482	2297	2110 to 2854 ng/ml
Control II	1549	1595	1239 to 1859 ng/ml

7. <u>Performances</u>		Measured value
Normal Plasmas	N = 10	2.4
PZ deficient plasma		<0.10
		1 to 4 µg/ml
		≤0.15 µg/ml

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 05/05/2014

QC Manager :

*B. S. DE
D. L. COURT*

S. LECOURT