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# **CERTIFICATE OF ANALYSIS**

**ZYMUTEST  
Protein Z ELISA kit**

**#RK031A**

**Lot : F1600851**

**Expiration date : 2019-02-08**

*SQE*

## ANALYSIS CERTIFICATE

**Protein Z ELISA kit**

**Lot : F1600851**

**QC release : 08/09/2016**

**Expiration date : 2019-02-08**

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) PZ pre-coated plate	12x8 wells	30	F1600854	2019-02-08
Protein Z Calibrator	3 vials	30	F1600855	2019-02-10
Anti-(h)-PZ-HRP immunoconjugate	3 vials	30	F1600858	2019-02-16
Sample diluent	2x50	30	F1600788	2020-01-22
Wash solution	1x50	42	F1600690	2019-12-18
Conjugate diluent	1x25	42	150914G	2019-03
PZ Control I	1 vial	30	F1600856	2019-02-12
PZ Control II	1 vial	30	F1600857	2019-02-12
TMB substrate	1x25		150915D02	2019-09-30
Sulfuric Acid 0,45M	1x6	42	F1600128	2019-07-08

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Analytical data	Specifications																																										
<b>1. <u>Reactivity</u></b>																																											
A450 for standard 80 ng/ml: <span style="float: right;">1,950</span>	≥ 1.50																																										
<b>2. <u>Plasma Standard</u></b>																																											
Concentration <span style="float: right;">95 ng/ml</span>	90-110 ng/ml																																										
CV <span style="float: right;">7,5 %</span>	≤ 10 %																																										
<b>3. <u>Blank value</u></b>																																											
A450 for sample diluent : <span style="float: right;">0,001</span>	< 0.100																																										
SD : <span style="float: right;">0,003</span>	< 0.015																																										
<b>4. <u>Calibration curve</u></b>																																											
Curve Fitting : <span style="float: right;">polynom 2</span>																																											
<table border="1" 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;">95 ng/ml</td> <td style="text-align: center;">2,039</td> <td style="text-align: center;">0,049</td> <td style="text-align: center;">2,4</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;">&lt;10</td> </tr> <tr> <td style="text-align: center;">47,5 ng/ml</td> <td style="text-align: center;">1,452</td> <td style="text-align: center;">0,034</td> <td style="text-align: center;">2,4</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;">&lt;10</td> </tr> <tr> <td style="text-align: center;">23,8 ng/ml</td> <td style="text-align: center;">0,860</td> <td style="text-align: center;">0,018</td> <td style="text-align: center;">2,1</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;">&lt;10</td> </tr> <tr> <td style="text-align: center;">9,5 ng/ml</td> <td style="text-align: center;">0,390</td> <td style="text-align: center;">0,011</td> <td style="text-align: center;">2,7</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;">&lt;10</td> </tr> <tr> <td style="text-align: center;">4,75 ng/ml</td> <td style="text-align: center;">0,210</td> <td style="text-align: center;">0,010</td> <td style="text-align: center;">4,9</td> <td style="text-align: center;">N = 10</td> <td style="text-align: center;">&lt;10</td> </tr> <tr> <td style="text-align: center;">0 ng/ml</td> <td style="text-align: center;">0,001</td> <td style="text-align: center;">0,003</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 (%)	95 ng/ml	2,039	0,049	2,4	N = 10	<10	47,5 ng/ml	1,452	0,034	2,4	N = 10	<10	23,8 ng/ml	0,860	0,018	2,1	N = 10	<10	9,5 ng/ml	0,390	0,011	2,7	N = 10	<10	4,75 ng/ml	0,210	0,010	4,9	N = 10	<10	0 ng/ml	0,001	0,003	/	N = 10		
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<b>5. <u>Detection threshold</u></b>																																											
Concentration <0,10	≤ 0.25 µg/ml																																										
<b>6. <u>Controls</u></b>																																											
Target value ng/ml	Measured value ng/ml	Acceptancy range																																									
Control I	2913	2647	2476 to 3350 ng/ml																																								
Control II	1324	1248	1059 to 1589 ng/ml																																								
<b>7. <u>Performances</u></b>																																											
Normal Plasmas	N = 10	Measured value 2,3	1 to 4 µg/ml																																								
PZ deficient plasma		<0,10	≤0.15 µg/ml																																								

<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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**Date :** 08/09/2016

**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** F1600851



2019-02-08

<u>Values assigned / Valeurs cibles (*)</u>
<b>Calibrator / Calibrateur</b> LOT : F1600855 Concentration : 95 ng/mL
<b>Control / Contrôle CI</b> LOT : F1600856 Target value / Valeur cible : 2913 ng/mL Acceptance range / Domaine d'acceptation : [ 2476 - 3350 ] ng/mL
<b>Control / Contrôle CII</b> LOT : F1600857 Target value / Valeur cible : 1324 ng/mL Acceptance range / Domaine d'acceptation : [ 1059 - 1589 ] ng/mL

(\*) Standardization / Standardisation : NIA

Note: Curve fitting suitable for RK031A using Magellan software (Tecan ®) : second-degree polynomial (\*\*), third-degree polynomial (\*\*), 4 parameters marquardt, 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 : 08/09/2016

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT