

ANALYSIS CERTIFICATE

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CERTIFICATE OF ANALYSIS

**ZYMUTEST
tPA Ag ELISA kit**

#RK011A

Lot : F1700406 Expiration date : 2019-11-23



ANALYSIS CERTIFICATE

tPA Ag ELISA kit

Lot : F1700406

QC Release : 26/07/2017

Expiration date : 2019-11-23

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) tPA pre-coated plate	12x8 wells	30	F1700647	2019-11-23
tPA standard 0	1 vial	42	F1700347	2020-09-17
tPA standard 1	1 vial	42	F1700671	2020-11-23
tPA standard 2	1 vial	42	F1700672	2020-11-23
tPA standard 3	1 vial	42	F1700673	2020-11-23
Anti-(h)-tPA-HRP immunoconjugate	3 vials	30	F1700678	2019-12-02
F-Sample diluent	2x50	42	F1700770	2020-12-22
Wash solution	1x50	42	F1700796	2020-12-28
Conjugate diluent	1x25	42	F1700772	2020-12-23
Plasma Control I	1 vial	42	F1700434	2020-10-01
Plasma Control II	1 vial	42	F1700435	2020-10-01
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 at 19 ng/mL : 2,023	≥ 1,40																														
2. <u>Plasma Standard 0</u> Concentration 0 ng/ml <u>Plasma Standard 1</u> Concentration 7 ng/ml CV 5,1 % <u>Plasma Standard 2</u> Concentration 14 ng/ml CV 3,6 % <u>Plasma Standard 3</u> Concentration 21 ng/ml CV 3,4 %	0 ng/ml* 6-9 ng/ml* ≤ 10 % 13-18 ng/ml* ≤ 10 % 19-27 ng/ml* ≤ 10 %																														
3. <u>Blank value</u> A450 for sample diluent : 0,021 SD : 0,008	< 0.100 < 0.015																														
4. <u>Calibration curve</u> Curve Fitting : Polynom 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>21 ng/ml</td> <td style="color: red;">2,235</td> <td style="color: red;">0,14</td> <td style="color: red;">6,4</td> <td>N = 10</td> <td>≤ 10</td> </tr> <tr> <td>14 ng/ml</td> <td style="color: red;">1,485</td> <td style="color: red;">0,122</td> <td style="color: red;">7,6</td> <td>N = 10</td> <td>≤ 10</td> </tr> <tr> <td>7 ng/ml</td> <td style="color: red;">0,809</td> <td style="color: red;">0,045</td> <td style="color: red;">5,6</td> <td>N = 10</td> <td>≤ 10</td> </tr> <tr> <td>0 ng/ml</td> <td style="color: red;">0,080</td> <td style="color: red;">0,014</td> <td style="color: red;">/</td> <td>N = 10</td> <td></td> </tr> </tbody> </table>	Conc.	OD	SD	CV (%)	N	CV (%)	21 ng/ml	2,235	0,14	6,4	N = 10	≤ 10	14 ng/ml	1,485	0,122	7,6	N = 10	≤ 10	7 ng/ml	0,809	0,045	5,6	N = 10	≤ 10	0 ng/ml	0,080	0,014	/	N = 10		
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5. <u>Detection threshold</u>	Concentration <0,5 ng/ml	≤ 0.5 ng/ml																													
6. <u>Controls</u>	Target value ng/ml	Measured value ng/ml	Acceptancy range																												
Control I	11,5	11,4	9,8 to 13,2 ng/ml																												
Control II	3,1	3,1	2,5 to 3,7 ng/ml																												

* Indicative Rate

Comments :



PASSED IN COMPLIANCE

Date : 26/07/2017

QC Manager : S. LECOURT



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ENGLISH / FRANÇAIS



Zymutest tPA Antigen / tPA Antigène

REF RK011A

Assay of tPA Antigen by ELISA / Dosage ELISA du tPA Antigène

For in vitro use only / Utilisation in vitro exclusivement

LOT F1700406



2019-11-23

<u>Values assigned / Valeurs cibles (*)</u>	
Standard Plasma / Plasma Standard 0 LOT : F1700347	
Concentration :	0 ng/mL
Standard Plasma / Plasma Standard 1 LOT : F1700671	
Concentration :	7 ng/mL
Standard Plasma / Plasma Standard 2 LOT : F1700672	
Concentration :	14 ng/mL
Standard Plasma / Plasma Standard 3 LOT : F1700673	
Concentration :	21 ng/mL
Control / Contrôle CI LOT : F1700434	
Target value / Valeur cible :	11,5 ng/mL
Acceptance range / Domaine d'acceptation :	[9,8 – 13,2] ng/mL
Control / Contrôle CII LOT : F1700435	
Target value / Valeur cible :	3,1 ng/mL
Acceptance range / Domaine d'acceptation :	[2,5 – 3,7] ng/mL

(*) Standardization / Standardisation : Calibration and controls are related to International Standard from NIBSC 94/730

Note: Curve fitting suitable for RK011A 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 RK011A 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 : 26/07/2017

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT