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# **CERTIFICATE OF ANALYSIS**

**ZYMUTEST  
Factor IX ELISA kit**

**#RK032A**

**Lot : F1600151**

**Expiration date : 2018-06-17**



## ANALYSIS CERTIFICATE

**Factor IX ELISA kit**

**Lot : F1600151**

**QC release : 18/03/2016**

**Expiration date : 2018-06-17**

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) FIX pre-coated plate	12x8 wells	30	F1600277	2018-08-18
Plasma FIX Calibrator	3 vials	42	F1600004	2019-06-17
Anti-(h)-FIX-HRP immunoconjugate	3 vials	30	F1600289	2018-08-25
Sample diluent	2x50	30	F1600253	2019-08-22
Wash solution	1x50	42	F1600026	2019-06-24
Conjugate diluent	1x25	42	150914G	2019-03
Plasma FIX Control I	1 vial	42	141217D	2018-06
Plasma FIX Control II	1 vial	42	141217E	2018-06
TMB substrate	1x25		150914	2019-05
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 calibrator at 100% : <span style="float: right;">1,510</span>	≥ 1,50																																										
<b>2. <u>Calibrator Plasma</u></b> Concentration <span style="float: right;">111 %</span> CV <span style="float: right;">3,1 %</span>	≥ 100% ≤ 10 %																																										
<b>3. <u>Blank value</u></b> A450 for sample diluent : <span style="float: right;">0,022</span> SD : <span style="float: right;">0,003</span>	< 0.100 < 0.015																																										
<b>4. <u>Calibration curve</u></b> Curve Fitting : <span style="float: right;">polynomial 2</span> <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 ≥10</th> <th style="width: 15%;">CV (%)</th> </tr> </thead> <tbody> <tr> <td>C</td> <td>1,575</td> <td>0,04</td> <td>2,3</td> <td>10</td> <td>&lt;10</td> </tr> <tr> <td>C/2</td> <td>1,040</td> <td>0,03</td> <td>2,4</td> <td>10</td> <td>&lt;10</td> </tr> <tr> <td>C/4</td> <td>0,626</td> <td>0,01</td> <td>2,3</td> <td>10</td> <td>&lt;10</td> </tr> <tr> <td>C/10</td> <td>0,293</td> <td>0,01</td> <td>1,8</td> <td>10</td> <td>&lt;10</td> </tr> <tr> <td>C/20</td> <td>0,170</td> <td>0,01</td> <td>4,4</td> <td>10</td> <td>&lt;10</td> </tr> <tr> <td>0</td> <td>0,022</td> <td>0,003</td> <td>/</td> <td>10</td> <td>&lt;10</td> </tr> </tbody> </table>	Conc.	OD	SD	CV (%)	N ≥10	CV (%)	C	1,575	0,04	2,3	10	<10	C/2	1,040	0,03	2,4	10	<10	C/4	0,626	0,01	2,3	10	<10	C/10	0,293	0,01	1,8	10	<10	C/20	0,170	0,01	4,4	10	<10	0	0,022	0,003	/	10	<10	
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<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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**Date : 18/03/2016**

**QC Manager :**

**S. LECOURT**



## Zymutest Factor IX / *Facteur IX*

**REF** RK032A

### Factor IX Antigen / *Facteur IX Antigène*

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

**LOT** F1600151



2018-06-17

<u>Values assigned / Valeurs cibles (*)</u>
<b>Calibrator / Calibrateur</b> LOT : F1600004 Concentration : 111 %
<b>Control / Contrôle CI</b> LOT : 141217D Target value / <i>Valeur cible</i> : 87 % Acceptance range / <i>Domaine d'acceptation</i> : [74 - 100] %
<b>Control / Contrôle CII</b> LOT : 141217E Target value / <i>Valeur cible</i> : 38 % Acceptance range / <i>Domaine d'acceptation</i> : [30 - 46] %

(\*) Standardization / *Standardisation* : Calibrator and controls are indirectly qualified against the 3<sup>rd</sup> International Standard Factors II, VII, IX, X, Plasma (99/826)

Note: Curve fitting suitable for RK032A using Magellan software (Tecan ®) : second-degree polynomial (\*\*), third-degree polynomial (\*\*), 4 parameters, 4 parameters marquardt, 5 parameters marquardt, cubic spline, akima, and point to point / *Les modes d'interpolation adaptés pour RK032A sur le logiciel Magellan (Tecan ®) sont : polynôme de degré 2 (\*\*), polynôme de degré 3 (\*\*), 4 paramètres, 4 paramètres marquardt, 5 paramètres marquardt, spline cubique, akima, et point par point.*

(\*\*) Best fit suggested / *Mode d'interpolation à favoriser*

Approved Date / *Date d'Approbation* : 18.03.2016

Quality Control Manager / *Responsable Contrôle Qualité* : S. LECOURT