



HYPHEN BioMed  
155 rue d'Eragny  
95000 Neuville-sur-Oise  
France



A Company of Sysmex Group

## CERTIFICATE OF ANALYSIS

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### ZYMUTEST HIA IgG Elisa Kit

**#RK040A**

**Lot : FE3218**

**Expiration date : 2028-03-10**



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Lot : FE3218

QC Release : ...

Expiration date : 2028-03-10

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Heparin coated plate	12x8 wells	30	FE3650	2028-03-17
HIA IgG Positive control	3 vials	30	FE3705	2028-03-27
Anti-(h)-IgG -HRP immunoconjugate	3 vials	42	FE3761	2029-03-29
HIA Sample diluent	2x50	30	FE3584	2028-03-10
Wash solution	1x50	42	FE0011	2028-06-15
Conjugate diluent	1x25	42	FE3391	2029-02-12
Cell lysate	3 vials	30	FE3649	2028-03-20
Negative control	3 vials	42	FE3587	2029-03-05
TMB substrate	1x25		250301D02	2029-03-31
Sulfuric Acid 0,45M	1x6	42	FE0017	2028-06-19

FAS



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QC Release : 26...11. 2025

Expiration date : 2028-03-10

Analytical data	Specifications
<b>1. <u>Reactivity</u></b>	
A450 for Positive control : <span style="float: right;"><b>1.872</b></span>	≥ 1.00
CV: <b>2.3</b>	≤ 10%
A450 for Negative control : <span style="float: right;"><b>0.049</b></span>	≤ 0.25

<b>2. <u>Blank value</u></b>	
A450 for sample diluent = <span style="float: right;"><b>0.018</b></span>	< 0.100
SD = <span style="float: right;"><b>0.003</b></span>	< 0.015
N = <span style="float: right;"><b>12</b></span>	N ≥ 10

<b>3. <u>Pathological Plasmas Tested</u></b>									
N= 3	N ≥ 2								
<table border="1" style="margin: auto;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 50%;">Measured value for A450</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">P1</td> <td style="text-align: center;"><b>1.703</b></td> </tr> <tr> <td style="text-align: center;">P2</td> <td style="text-align: center;"><b>2.180</b></td> </tr> <tr> <td style="text-align: center;">P3</td> <td style="text-align: center;"><b>1.662</b></td> </tr> </tbody> </table>		Measured value for A450	P1	<b>1.703</b>	P2	<b>2.180</b>	P3	<b>1.662</b>	OD Patho ≥ 0.300
	Measured value for A450								
P1	<b>1.703</b>								
P2	<b>2.180</b>								
P3	<b>1.662</b>								

<b>4. <u>Normal Plasmas Tested</u></b>			
N= 35	Mean A450= <b>0.082</b>	SD= <b>0.046</b>	N ≥ 30
Mean+2SD= <b>0.174</b>			M+2SD ≤ 0.30

<p><u>Comments :</u></p>	<p><b>PASSED IN COMPLIANCE</b></p>
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Date : 26...11. 2025

QC Manager :

Sophie LECOURT  
Technical Director