



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: FC1479

Expiration date: 2025-12-01

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Analytical data	Specifications
<b>1. <u>Reactivity</u></b>	
A450 for Positive control: <span style="float: right;"><b>1.582</b></span>	≥ 1.00
CV: <span style="float: right;"><b>3%</b></span>	≤ 10%
A450 for Negative control: <span style="float: right;"><b>0.064</b></span>	≤ 0.25

<b>2. <u>Blank value</u></b>	
A450 for sample diluent = <span style="float: right;"><b>0.019</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-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>Measured value for A450</th> </tr> </thead> <tbody> <tr> <td>P1</td> <td style="text-align: center;"><b>1.659</b></td> </tr> <tr> <td>P2</td> <td style="text-align: center;"><b>1.420</b></td> </tr> <tr> <td>P3</td> <td style="text-align: center;"><b>1.084</b></td> </tr> </tbody> </table>		Measured value for A450	P1	<b>1.659</b>	P2	<b>1.420</b>	P3	<b>1.084</b>	OD Patho ≥ 0.300
	Measured value for A450								
P1	<b>1.659</b>								
P2	<b>1.420</b>								
P3	<b>1.084</b>								

<b>4. <u>Normal Plasmas Tested</u></b>	
N= 33      Mean A450= <b>0.115</b> SD= <b>0.077</b>	N ≥ 30
Mean+2SD= <b>0.269</b>	M+2SD ≤ 0.30

<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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Date: 2023-07-25

QC Manager: **S. LECOURT**



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Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Heparin coated plate	12x8 wells	30	FC1473	2025-12-01
HIA IgG Positive control	3 vials	30	FC1557	2025-12-15
Anti-(h)-IgG -HRP immunoconjugate	3 vials	42	FC1598	2026-12-14
HIA Sample diluent	2x50	30	FC1551	2025-12-12
Wash solution	1x50	42	FC0034	2026-06-15
Conjugate diluent	1x25	42	FC0128	2026-06-30
Cell lysate	3 vials	30	FC1501	2025-12-08
Negative control	3 vials	42	FC1649	2026-12-21
TMB substrate	1x25		220106D03	2026-01-31
Sulfuric Acid 0,45M	1x6	42	FC0223	2026-07-15

*Jes.*