



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 : FF0423 / FF0480 Expiration date : 2028-07-28

SAS



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QC Release : ... 17 AVR. 2026

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Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Heparin coated plate	12x8 wells	30	FF0576	2028-08-19
HIA IgG Positive control	3 vials	30	FF0701	2028-09-01
Anti-(h)-IgG -HRP immunoconjugate	3 vials	42	FF0757	2029-09-06
HIA Sample diluent	2x50	30	FF0457	2028-07-28
Wash solution	1x50	42	FE3949	2029-04-16
Conjugate diluent	1x25	42	FE3391	2029-02-12
Cell lysate	3 vials	30	FF0668	2028-08-25
Negative control	3 vials	42	FF0526	2029-08-10
TMB substrate	1x25		250904D02	2029-09-30
Sulfuric Acid 0,45M	1x6	42	FE4263	2029-05-28

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Analytical data	Specifications
1. <u>Reactivity</u> A450 for Positive control : 1.875 CV: 5.8 A450 for Negative control : 0.039	≥ 1.00 $\leq 10\%$ ≤ 0.25

2. <u>Blank value</u> A450 for sample diluent = 0.010 SD = 0.002 N = 12	< 0.100 < 0.015 $N \geq 10$
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3. <u>Pathological Plasmas Tested</u> N= 3 <table border="1" style="margin-left: 40px;"> <thead> <tr> <th></th> <th>Measured value for A450</th> </tr> </thead> <tbody> <tr> <td>P1</td> <td style="text-align: center;">1.932</td> </tr> <tr> <td>P2</td> <td style="text-align: center;">2.044</td> </tr> <tr> <td>P3</td> <td style="text-align: center;">1.786</td> </tr> </tbody> </table>		Measured value for A450	P1	1.932	P2	2.044	P3	1.786	N ≥ 2 OD Patho ≥ 0.300
	Measured value for A450								
P1	1.932								
P2	2.044								
P3	1.786								

4. <u>Normal Plasmas Tested</u> N= 35 Mean A450= 0.059 SD= 0.045 Mean+2SD= 0.149	N ≥ 30 M+2SD ≤ 0.30
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<u>Comments :</u> 	<p>PASSED IN COMPLIANCE</p>
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Date :

QC Manager :

Quality Control Approval

17 AVR. 2026

S. LECOURT