



HYPHEN BioMed

155 rue d'Eragny

95000 Neuville-sur-Oise

France



CERTIFICATE OF ANALYSIS

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**ZYMUTEST
HIA IgG Elisa Kit**

#RK040A

Lot : FF1416

Expiration date : 2028-03-10

SND



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QC Release : 11 JUIN 2026

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

5000



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Analytical data			Specifications								
1. <u>Reactivity</u>											
A450 for Positive control :	1.872		≥ 1.00								
CV:	2.3		≤ 10%								
A450 for Negative control :	0.049		≤ 0.25								
2. <u>Blank value</u>											
A450 for sample diluent =	0.018		< 0.100								
SD =	0.003		< 0.015								
N =	12		N ≥ 10								
3. <u>Pathological Plasmas Tested</u>											
N= 3			N ≥ 2								
<table><tr><td></td><td>Measured value for A450</td></tr><tr><td>P1</td><td>1.703</td></tr><tr><td>P2</td><td>2.180</td></tr><tr><td>P3</td><td>1.662</td></tr></table>				Measured value for A450	P1	1.703	P2	2.180	P3	1.662	OD Patho ≥ 0.300
	Measured value for A450										
P1	1.703										
P2	2.180										
P3	1.662										
4. <u>Normal Plasmas Tested</u>											
N= 35	Mean A450= 0.082	SD= 0.046	N ≥ 30								
Mean+2SD= 0.174			M+2SD ≤ 0.30								

Comments :	 PASSED IN COMPLIANCE
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Date : Quality Control Approval

QC Manager : 

11 JUIN 2026

 S.MONEUS