



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

CERTIFICATE OF ANALYSIS

 **HYPHEN**
BioMed
A Company of Sysmex Group

CERTIFICATE OF ANALYSIS

**ZYMUTEST
HIA IgG Elisa Kit**

#RK040A

Lot : FF1828 / FF1863 Expiration date : 2029-02-02

SD



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FF1828 /

Lot : FF1863

QC Release : ... 09 SEP. 2026

Expiration date : 2029-02-02

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Heparin coated plate	12x8 wells	30	FF1862	2029-02-02
HIA IgG Positive control	3 vials	30	FF1928	2029-02-16
Anti-(h)-IgG -HRP immunoconjugate	3 vials	42	FF1927	2030-02-14
HIA Sample diluent	2x50	30	FF1877	2029-02-09
Wash solution	1x50	42	FF1466	2029-12-04
Conjugate diluent	1x25	42	FF1467	2029-12-03
Cell lysate	3 vials	30	FF1876	2029-02-11
Negative control	3 vials	42	FF1933	2030-02-11
TMB substrate	1x25		250904D02	2029-09-30
Sulfuric Acid 0,45M	1x6	42	FF1007	2029-10-01

Snp



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Analytical data	Specifications
1. Reactivity	
A450 for Positive control : 1.948	≥ 1.00
CV: 3.1	$\leq 10\%$
A450 for Negative control : 0.047	≤ 0.25

2. Blank value	
A450 for sample diluent = 0.018	< 0.100
SD = 0.001	< 0.015
N = 12	$N \geq 10$

3. Pathological Plasmas Tested									
N= 3	$N \geq 2$								
<table><tr><td></td><td>Measured value for A450</td></tr><tr><td>P1</td><td>2.256</td></tr><tr><td>P2</td><td>2.444</td></tr><tr><td>P3</td><td>1.912</td></tr></table>		Measured value for A450	P1	2.256	P2	2.444	P3	1.912	OD Patho ≥ 0.300
	Measured value for A450								
P1	2.256								
P2	2.444								
P3	1.912								

4. Normal Plasmas Tested	
N= 33 0.077 SD= 0.044	$N \geq 30$
Mean+2SD= 0.165	$M+2SD \leq 0.30$

Comments :	 PASSED IN COMPLIANCE
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Date : Quality Control Approval

QC Manager :

09 SEP. 2026

S.MONEUS

