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

CERTIFICATE OF ANALYSIS

HYPHEN BioMed
A Company of Sysmex Group

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ZYMUTEST
HIA IgG Elisa Kit

#RK040A

Lot : FD1265 **Expiration date :** 2027-02-12

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HIA IgG Elisa Kit **Lot : FD1265**

QC Release : ... **Expiration date : 2027-02-12**

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Heparin coated plate	12x8 wells	30	FD1740	2027-02-26
HIA IgG Positive control	3 vials	30	FD1848	2027-03-12
Anti-(h)-IgG -HRP immunoconjugate	3 vials	42	FD1850	2028-03-09
HIA Sample diluent	2x50	30	FD1631	2027-02-12
Wash solution	1x50	42	FD1330	2027-12-22
Conjugate diluent	1x25	42	FD1442	2028-01-03
Cell lysate	3 vials	30	FD1803	2027-03-08
Negative control	3 vials	42	FD1266	2027-12-10
TMB substrate	1x25		240508D01	2028-05-31
Sulfuric Acid 0,45M	1x6	42	FD1506	2028-01-12

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Analytical data			Specifications
1. Reactivity			
A450 for Positive control :		**1.676**	≥ 1.00
	CV:	**3.1**	≤ 10%
A450 for Negative control :		**0.059**	≤ 0.25
2. Blank value			
A450 for sample diluent =		**0.028**	< 0.100
SD =		**0.003**	< 0.015
N =		**12**	N ≥ 10

3. Pathological Plasmas Tested — N ≥ 2

N= **3**

	Measured value for A450
P1	**1.689**
P2	**2.288**
P3	**2.000**

OD Patho ≥ 0.300

4. Normal Plasmas Tested — N ≥ 30

N= **35** Mean A450= **0.069** SD= **0.033**

Mean+2SD= **0.135** — M+2SD ≤ 0.30

Comments :

PASSED IN COMPLIANCE

Date : 18.10.2024

QC Manager : Claire DUNOIS ..... Dir. Etudes Clin. & Val.