



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

HYPHEN
BioMed
A Company of Sysmex Group

CERTIFICATE OF ANALYSIS

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**ZYMUTEST
HIA IgG Elisa Kit**

#RK040A

Lot : F2000177

Expiration date: 2022-08-19

SAS



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QC Release: 2020-04-02

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Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Heparin coated plate	12x8 wells	30	F2000315	2022-08-26
HIA IgG Positive control	3 vials	30	F2000356	2022-09-12
Anti-(h)-IgG -HRP immunoconjugate	3 vials	42	F2000354	2023-09-04
HIA Sample diluent	2x50	30	F2000284	2022-08-19
Wash solution	1x50	42	F2000037	2023-06-27
Conjugate diluent	1x25	42	F1900898	2022-12-27
Cell lysate	3 vials	30	F2000178	2022-08-30
Negative control	3 vials	42	F2000171	2023-07-21
TMB substrate	1x25		190705D01	2023-07-30
Sulfuric Acid 0,45M	1x6	42	F1903262	2023-05-29

976



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Analytical data	Specifications
1. <u>Reactivity</u>	
A450 for Positive control : 1.63	≥ 1.00
CV: 6.6	≤ 10%
A450 for Negative control : 0.08	≤ 0.25

2. <u>Blank value</u>	
A450 for sample diluent = 0.06	< 0.100
SD = 0.006	< 0.015
N = 12	N ≥ 10

3. <u>Pathological Plasmas Tested</u>									
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;">1.07</td> </tr> <tr> <td>P2</td> <td style="text-align: center;">0.91</td> </tr> <tr> <td>P3</td> <td style="text-align: center;">0,94</td> </tr> </tbody> </table>		Measured value for A450	P1	1.07	P2	0.91	P3	0,94	OD Patho ≥ 0.300
	Measured value for A450								
P1	1.07								
P2	0.91								
P3	0,94								

4. <u>Normal Plasmas Tested</u>	
N= 35 Mean A450= 0.09 SD= 0.03	N ≥ 30
Mean+2SD= 0.15	M+2SD ≤ 0.30

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2020-04-02

QC Manager :

S. LECOURT