



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



A Company of Sysmex Group

CERTIFICATE OF ANALYSIS

CERTIFICATE OF ANALYSIS

ZYMUTEST HIA IgG Elisa Kit

#RK040A

Lot: FA1278

Expiration date: 2023-12-23

SOS



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HIA IgG Elisa Kit

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QC Release: 2021-08-24

Expiration date: 2023-12-23

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Heparin coated plate	12x8 wells	30	FA1285	2023-12-23
HIA IgG Positive control	3 vials	30	FA1299	2024-01-26
Anti-(h)-IgG -HRP immunoconjugate	3 vials	42	FA1288	2025-01-16
HIA Sample diluent	2x50	30	FA1295	2024-01-19
Wash solution	1x50	42	FA0934	2024-10-14
Conjugate diluent	1x25	42	FA1121	2024-11-18
Cell lysate	3 vials	30	FA1290	2024-01-13
Negative control	3 vials	42	FA1297	2025-01-20
TMB substrate	1x25		210302D01	2025-03-30
Sulfuric Acid 0,45M	1x6	42	FA1281	2024-12-24

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Analytical data	Specifications
1. <u>Reactivity</u> A450 for Positive control : 1.77 <div style="text-align: right; margin-left: 100px;">CV: 6.1</div> A450 for Negative control : 0.074	≥ 1.00 $\leq 10\%$ ≤ 0.25

2. <u>Blank value</u> A450 for sample diluent = 0.018 SD = 0.002 N = 10	< 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;">1.24</td> </tr> <tr> <td>P2</td> <td style="text-align: center;">1.28</td> </tr> <tr> <td>P3</td> <td style="text-align: center;">2.54</td> </tr> </tbody> </table>		Measured value for A450	P1	1.24	P2	1.28	P3	2.54	$N \geq 2$ OD Patho ≥ 0.300
	Measured value for A450								
P1	1.24								
P2	1.28								
P3	2.54								

4. <u>Normal Plasmas Tested</u> N= 37 Mean A450= 0.073 SD= 0.044 Mean+2SD= 0.161	$N \geq 30$ $M+2SD \leq 0.30$
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Comments: 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date: 2021-08-24

QC Manager: S. LECOURT