



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

CERTIFICATE OF ANALYSIS



A Company of Sysmex Group

CERTIFICATE OF ANALYSIS

ZYMUTEST HIA IgG Elisa Kit

#RK040A

Lot : F1903065

Expiration date : 2022-04-15



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QC Release : 2019-12-23

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| Components | Volume (mL) | Exp. (months) | Lot # | Exp. date |
|-----------------------------------|-------------|---------------|-----------|------------|
| Heparin coated plate | 12x8 wells | 30 | F1903245 | 2022-05-27 |
| HIA IgG Positive control | 3 vials | 30 | F1903261 | 2022-06-03 |
| Anti-(h)-IgG -HRP immunoconjugate | 3 vials | 42 | F1903246 | 2023-05-25 |
| HIA Sample diluent | 2x50 | 30 | F1903216 | 2022-05-20 |
| Wash solution | 1x50 | 42 | F1900767 | 2022-12-06 |
| Conjugate diluent | 1x25 | 42 | F1900898 | 2022-12-27 |
| Cell lysate | 3 vials | 30 | F1903067 | 2022-04-15 |
| Negative control | 3 vials | 42 | F1900101 | 2022-07-07 |
| TMB substrate | 1x25 | | 190705D01 | 2023-07-30 |
| Sulfuric Acid 0,45M | 1x6 | 42 | F1900840 | 2023-12-23 |

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| Analytical data | Specifications |
|--|---|
| 1. <u>Reactivity</u> A450 for Positive control : 1.526 <div style="text-align: right;">CV: 5.5</div> A450 for Negative control : 0.046 | ≥ 1.00 $\leq 10\%$ ≤ 0.25 |

| | |
|--|---------------------------------------|
| 2. <u>Blank value</u> A450 for sample diluent = 0.025 SD = 0.003 N = 12 | < 0.100 < 0.015 $N \geq 10$ |
|--|---------------------------------------|

| 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="color: red;">0.953</td> </tr> <tr> <td>P2</td> <td style="color: red;">0.836</td> </tr> <tr> <td>P3</td> <td style="color: red;">0.832</td> </tr> </tbody> </table> | | Measured value for A450 | P1 | 0.953 | P2 | 0.836 | P3 | 0.832 | $N \geq 2$ OD Patho ≥ 0.300 |
|--|-------------------------|-------------------------|----|-------|----|-------|----|-------|---|
| | Measured value for A450 | | | | | | | | |
| P1 | 0.953 | | | | | | | | |
| P2 | 0.836 | | | | | | | | |
| P3 | 0.832 | | | | | | | | |

| | |
|---|----------------------------------|
| 4. <u>Normal Plasmas Tested</u> N= 35 Mean A450= 0.062 SD= 0.033 Mean+2SD= 0.128 | $N \geq 30$ $M+2SD \leq 0.30$ |
|---|----------------------------------|

| | |
|---------------------------|---|
| Comments : | <input checked="" type="checkbox"/> PASSED IN COMPLIANCE |
|---------------------------|---|

Date : 2019-12-23

QC Manager : S. LECOURT



ZYMUTEST HIA IgG

REF RK040A

**Qualitative assay for the detection of heparin-dependent antibodies of the IgG
isotype by ELISA/**

***Recherche des anticorps héparine dépendants d'isotype IgG
par ELISA.***

For in vitro diagnostic use only / Usage diagnostic in vitro exclusivement

LOT F1903065



2022-04-15

Positive Control / Contrôle positif LOT : **F1903261**

A450 (20 ± 1 °C) : **1.526**

% corresponding to the cut off value / % correspondant à la valeur seuil : **19.7**

Negative Control / Contrôle négatif LOT : **F1900101**

A450 : **≤ 0.25**

Note: When the assay is used at room temperature (18-25°C), the cut-off value is of **A450 = 0.30**. When working conditions are out of this temperature range, the positive control can be used for adjusting the cut-off value.

*/ Lorsque le kit est utilisé à température ambiante (18-25°C), la valeur seuil est définie pour **A450 = 0.30**. Lorsque les conditions de travail sont hors de cette zone de température, le contrôle positif peut être utilisé pour ajuster cette valeur seuil.*

Note: These values are obtained by bichromatic reading, at 450nm, using a reference wavelength at 620 nm / ces valeurs sont obtenues par lecture bichromatique, à 450nm, le filtre 620nm étant utilisé comme longueur d'onde de référence.

Approved Date / Date d'Approbation : 2019-12-23

Quality Control Manager / Responsable Contrôle Qualité : **S. LECOURT**

