



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

## CERTIFICATE OF ANALYSIS

**Product Description :** ZYMUTEST HIA IgG Monostrip

**Product Code :** RK041A

**Lot No. :** FA1240

**Expiration date :** 2023-07-21

| Components                       | Quantity     | Lot       | Expiration Date |
|----------------------------------|--------------|-----------|-----------------|
| Heparin pre-coated plate         | 4 (x8 wells) | FA0882    | 2023-10-20      |
| HIA IgG Positive Control         | 4 vials      | FA0884    | 2023-11-03      |
| Negative Control                 | 4 vials      | F2000173  | 2023-07-21      |
| Anti-(h)-IgG HRP immunoconjugate | 4 vials      | FA0878    | 2024-10-22      |
| HIA Sample diluent               | 2x12 ml      | FA0735    | 2023-09-23      |
| Wash solution                    | 2x12 ml      | FA0932    | 2024-10-14      |
| Cell Lysate                      | 4 vials      | FA0880    | 2023-10-23      |
| Conjugate diluent                | 1x10 ml      | FA1122    | 2024-11-18      |
| TMB                              | 1x10 ml      | 210506D01 | 2025-05-31      |
| Sulfuric Acid 0,45M              | 1x3 ml       | FA0936    | 2024-10-14      |

| Analytical Data      | Specification  | Result       |
|----------------------|--|--------------|
| Reactivity           | A450 for Positive Control $\geq 1.00$<br>A450 for Negative Control $\leq 0.25$ | 1.77<br>0.08 |
| Pathological Plasmas | A450 $\geq 0.300$  | PASS         |
| Blank                | $< 0.100$  | 0.03         |
| Normal Plasma        | M + 2SD $\leq 0.30$  | 0.15         |

*This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.*

Date of Approval : 2021-07-23

Quality Control Manager : S.LECOURT

