

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST Anti Annexin V IgM

Product Code : RK005B

Lot No. : F2000398

Expiration date : 2022-06-21

| Components | Quantity | Lot | Expiration Date |
|--|------------|-----------|-----------------|
| Annexin V pre-coated plate | 12x8 wells | F2000807 | 2022-11-27 |
| Anti-Annexin V IgM Standard | 3 vials | F2000661 | 2022-11-05 |
| Negative Control | 3 vials | F2000657 | 2023-10-27 |
| Anti-(h)-IgM μ HRP immunoconjugate | 3 vials | F2000824 | 2023-11-30 |
| Autoimmunity Sample diluent | 2x50 ml | F2000573 | 2023-10-16 |
| Wash solution | 1x50 ml | F2000802 | 2023-11-20 |
| Conjugate diluent | 1x25 ml | F1900006 | 2022-06-21 |
| TMB | 1x25 ml | 190705D01 | 2023-07-30 |
| Sulfuric Acid 0,45M | 1x6 ml | F2000078 | 2023-07-04 |

| Analytical Data | Specification | Result |
|--|---|--------|
| Reactivity | A450 for 75 AU/ml \geq 1.30 | 1.85 |
| Calibration Curve and Negative Control | Negative Control measured within acceptance range | PASS |
| Blank | < 0.100 | 0.005 |
| Normal Plasma | \leq 10 AU/ml | < 3 |
| Detection threshold | \leq 5 AU/ml | < 1 |

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

Date of Approval : 2020-07-16

Quality Control Manager :

S.LECOURT

