HYPHEN BioMed
A Company of Sysmex Group

HYPHEN BioMed
155 rue d'Eragny
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France

# CERTIFICATE OF ANALYSIS

**Product Description : ZYMUTEST PAI-1 Activity**

**Product Code : RK019A**

**Lot No. : FF0637**

**Expiration date : 2029-03-31**

| Components | Quantity | Lot | Expiration Date |
|---|---|---|---|
| tPA pre-coated plate | 12x8 wells | FF1149 | 2029-10-22 |
| (h) PAI-1 standard | 3 vials | FF0777 | 2029-09-03 |
| (h) PAI-1 Control I | 1 vial | FF0775 | 2029-09-03 |
| (h) PAI-1 Control II | 1 vial | FF0776 | 2029-09-03 |
| Anti-(h)-PAI-1 HRP immunoconjugate | 3 vials | FF0852 | 2029-09-20 |
| F-Sample diluent | 2x50 ml | FE4201 | 2029-05-23 |
| Wash solution | 1x50 ml | FE4202 | 2029-05-21 |
| Conjugate diluent | 1x25 ml | FE4203 | 2029-05-21 |
| TMB | 1x25 ml | 250301D02 | 2029-03-31 |
| Sulfuric Acid 0,45M | 1x6 ml | FF0723 | 2029-08-27 |

| Analytical Data | Specification | Result |
|---|---|---|
| Reactivity | A450 for 8 ng/ml ≥ 1.00 | 1.41 |
| Calibration Curve and Accuracy | Controls Measured Values within acceptance ranges | PASS |
| Blank | < 0.100 | 0.005 |
| Detection threshold | ≤ 0.5 ng/ml | < 0.1 ng/ml |

## *Calibration Curve for information*

| Conc. | C | C/2 | C/4 | C/10 | C/20 |
|---|---|---|---|---|---|
| OD | 1.602 | 1.069 | 0.64 | 0.273 | 0.155 |

| | Acceptance Range | MV |
|---|---|---|
| CI | [ 6.2 - 8.4 ] | 7.8 |
| CII | [ 2.6 - 3.8 ] | 3.3 |

MV = Measured value

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

Date of Approval : Quality Control Approval 04 JUIN 2026

Quality Control Manager : S.MONEUS