# 5-Diagnostics

# Certificate of Analysis

**Product:**     **12x8 well-strip ADAMTS-13 Elisa kit**

**Reference:** 5D-55501

**Lot:** 260212-10                                      **Expiration date:** 2027-05-15

Store at 2-8°C

## Kit composition:

| Component | Code Id | Lot | Expiration date | N vials/kit |
|---|---|---|---|---|
| EIA Dilution Buffer | SD | 250603-10 | 03/06/2028 | 2 |
| EIA Washing Buffer | WS | 250603-30 | 03/06/2028 | 1 |
| EIA Stop Solution | SA | 250603-40 | 03/06/2028 | 1 |
| Immuno-Conjugate Diluent | ICD | 250603-20 | 03/06/2028 | 1 |
| Micro ELISA Plate | COAT | 250604-10 | 04/06/2028 | 1 |
| Calibrator | CAL | 250606-10 | 06/06/2028 | 2 |
| Plasma Control High | C1 | 250606-20 | 06/06/2028 | 2 |
| Plasma Control Low | C2 | 250606-30 | 06/06/2028 | 2 |
| Immuno-Conjugate | IC | 250515-10 | 15/05/2027 | 1 |
| TMB/H2O2 Peroxidase Substrate | SU | 240101D01 | 31/01/2028 | 1 |

## Analytical results:

| Control parameter | Results | Specifications | Conclusion |
|---|---|---|---|
| Kit performances (20°C +/- 1°C) | A450 (1.0 IU/ml) = 1.57 | 1.20 – 2.50 | Passed |
|  | $\Delta$A450 (1.0-0.50 IU/ml) = 0.67 | > 0.40 | Passed |
|  | Blank (A450) = 0.069 | < 0.15 | Passed |
|  | Intra assay CV:  C1  4.17 %<br>                        C2 6.40 % | < 8% | Passed |
|  | Inter assay CV:  C1 4.10 %<br>                        C2 6.60 % | < 10% | Passed |
| Calibration curve linearity | $R^2$ = 0.9996 | $R^2 \geq 0.98$ | Passed |
| ADAMTS13 **calibrator IU/ml**<br>(Ref: WHO International Standard) | C =    1.28 | 0.80 – 1.40 | Passed |
| ADAMTS13 control **C1 (IU/ml)**<br>Mean, Acceptance range (+/-15%) | Mean C1 =   0.92 IU/ml<br>Range: 0.79-1.05 | 0.70 – 1.00<br>+/- 15% | Passed |
| ADAMTS13 control **C2 (IU/ml)** | Mean C2 = 0.48   IU/ml | 0.25 – 0.50 | Passed |

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| Mean, Acceptance range (+/- 20%) | Range: 0.39-0.57 | +/- 20% | |
|---|---|---|---|
| TMB-H2O2 substrate | Clear solution | Clear solution | Passed |
| Dilution buffer | pH = 7.52 à 20.5°C | pH 7.20 - 7.80 | Passed |
| Immuno-Conjugate diluent | pH = 7.53 à 20.5°C | pH 7.20 -7.80 | Passed |
| Wash solution (20x) | pH = 7.41 à 20.5°C (diluted) | pH 7.00 - 8.00 | Passed |
| Stop solution (sulfuric acid) tested tenfold diluted | pH = 1.20 | pH 1.00 +/-0.50 | Passed |

**Calibration curve:**



Gamme Calibrator

$y = -0{,}442x^2 + 2{,}0019x + 0{,}0092$
$R^2 = 0{,}9996$
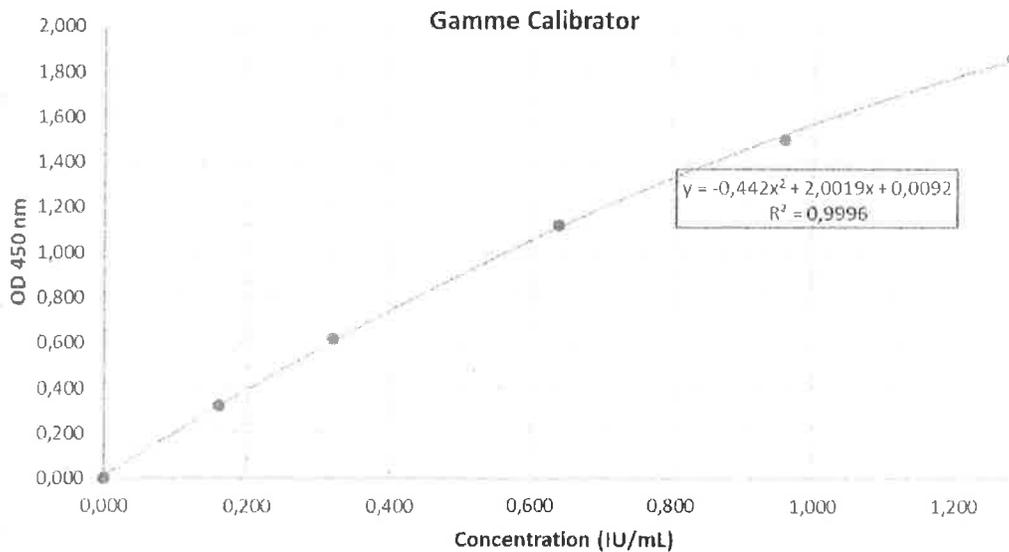
**Waivers:**

**Conclusions:**

| Currently tested lot | Specification |
|---|---|
| 260212-10 | Passed |

The ADAMTS-13 Elisa kit **lot 260212-10** is compliant with expected specifications and released.

**Date:** 2026-02-12

**Approved by:**