

## Certificate of Analysis

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

**Reference:** 5D-55501

**Lot:** 240119-10

**Expiration date:** 2025-02-02

Store at 2-8°C

**Kit composition:**

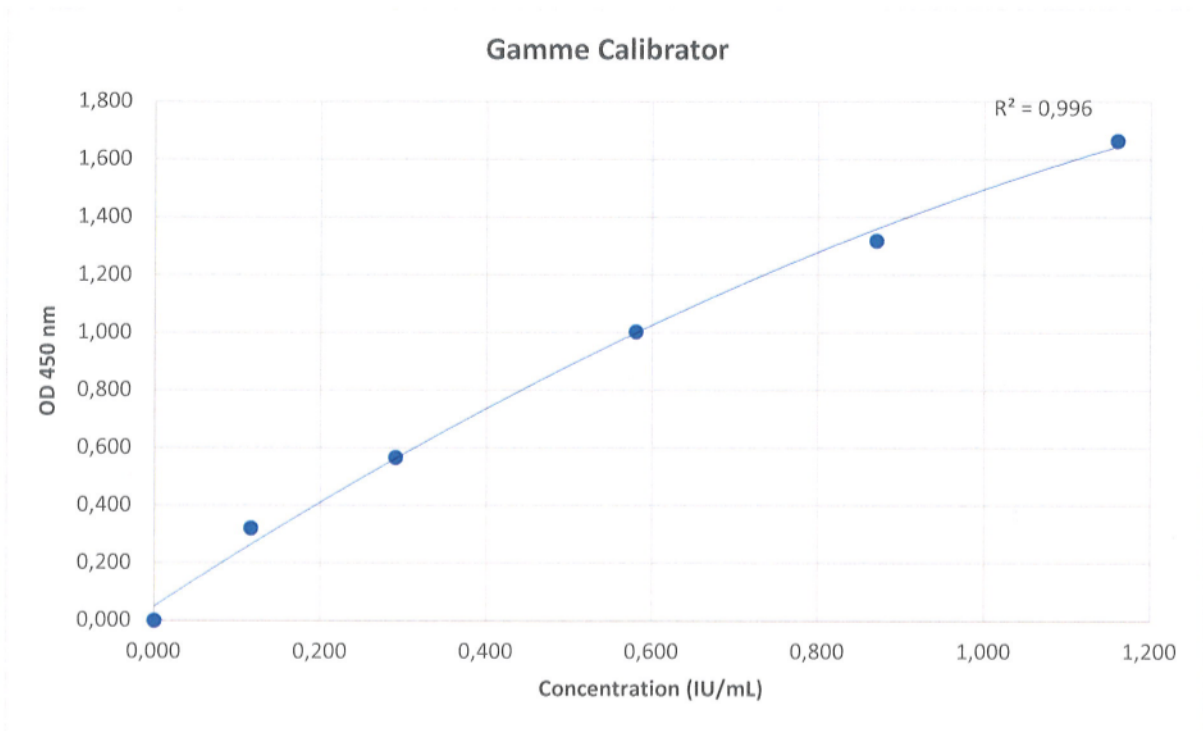
Component	Code Id	Lot	Expiration date	N vials/kit
Anti-ADAMTS13 Precoated plate	COAT	240115-10	2027-01	1
Anti-ADAMTS13-peroxidase (50x)	IC	230202-10	2025-02	1
ADAMTS13 calibrator	CAL	211126-11	2025-11	2
ADAMTS13 control C1	C1	211130-11	2025-11	2
ADAMTS13 control C2	C2	211130-21	2025-11	2
TMB-H2O2 substrate	SU	220201D05	2026-02	1
Dilution buffer	SD	230130-10	2026-01	2
Immuno-Conjugate diluent	ICD	220414-10	2025-04	1
Wash solution (20x)	WS	230629-10	2026-06	1
Stop solution (sulfuric acid)	SA	220411-20	2025-04	1

**Analytical results:**

Control parameter	Results	Specifications	Conclusion
Kit performances (20°C +/- 1°C)	A450 (1.0 IU/ml) = 1.50	1.20 – 2.50	Passed
	$\Delta$ A450 (1.0-0.50 IU/ml) = 0.61	> 0.40	Passed
	Blank (A450) = 0.054	< 0.15	Passed
	Intra assay CV: C1 5.77 % C2 4.79 %	< 8%	Passed
	Inter assay CV: C1 5.32 % C2 5.92 %	< 10%	Passed
Calibration curve linearity	R <sup>2</sup> = 0.996	R <sup>2</sup> ≥ 0.98	Passed
ADAMTS13 calibrator IU/ml (Ref: WHO International Standard)	C = 1.16	0.80 – 1.20	Passed
ADAMTS13 control C1 (IU/ml) Mean, Acceptance range (+/-15%)	Mean C1 = 0.87 IU/ml Range: 0.76-1.00	0.70 – 1.00 +/- 15%	Passed
ADAMTS13 control C2 (IU/ml) Mean, Acceptance range (+/- 20%)	Mean C2 = 0.47 IU/ml Range: 0.39-0.54	0.25 – 0.45 +/- 20%	Passed (waiver)

TMB-H <sub>2</sub> O <sub>2</sub> substrate	Clear solution	Clear solution	Passed
Dilution buffer	pH = 7.48	pH 7.20 - 7.80	Passed
Immuno-Conjugate diluent	pH = 7.50	pH 7.20 - 7.80	Passed
Wash solution (20x)	pH = 7.46 (diluted)	pH 7.00 - 8.00	Passed
Stop solution (sulfuric acid) tested tenfold diluted	pH = 1.32	pH 1.00 +/- 0.50	Passed

**Calibration curve:**



**Waivers:**

**Conclusions:**

Currently tested lot	Specification
240119-10	Passed

The ADAMTS-13 Elisa kit lot **240119-10** is compliant with expected specifications and released.

**Date:** January 22, 2024

**Approved by:**

Barbara Stix  
