

## Certificate of Analysis

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

**Reference:** 5D-55501

**Lot:** 240611-10

**Expiration date:** 2025-11-26

Store at 2-8°C

**Kit composition:**

Component	Code Id	Lot	Expiration date	N vials/kit
EIA Dilution Buffer	SD	240610-10	2027-06	2
EIA Washing Buffer	WS	230629-10	2026-06	1
EIA Stop Solution	SA	240328-10	2027-03	1
Immuno Conjugate Diluent	ICD	240329-10	2027-03	1
Micro ELISA Plate	COAT	240610-10	2027-06	1
Calibrator	CAL	211126-11	2025-11	2
Plasma Control High	C1	211130-11	2025-11	2
Plasma Control Low	C2	211130-21	2025-11	2
Immuno Conjugate	IC	240610-20	2026-06	1
TMB/H <sub>2</sub> O <sub>2</sub> Peroxydase Substrate	SU	220201D05	2026-02	1

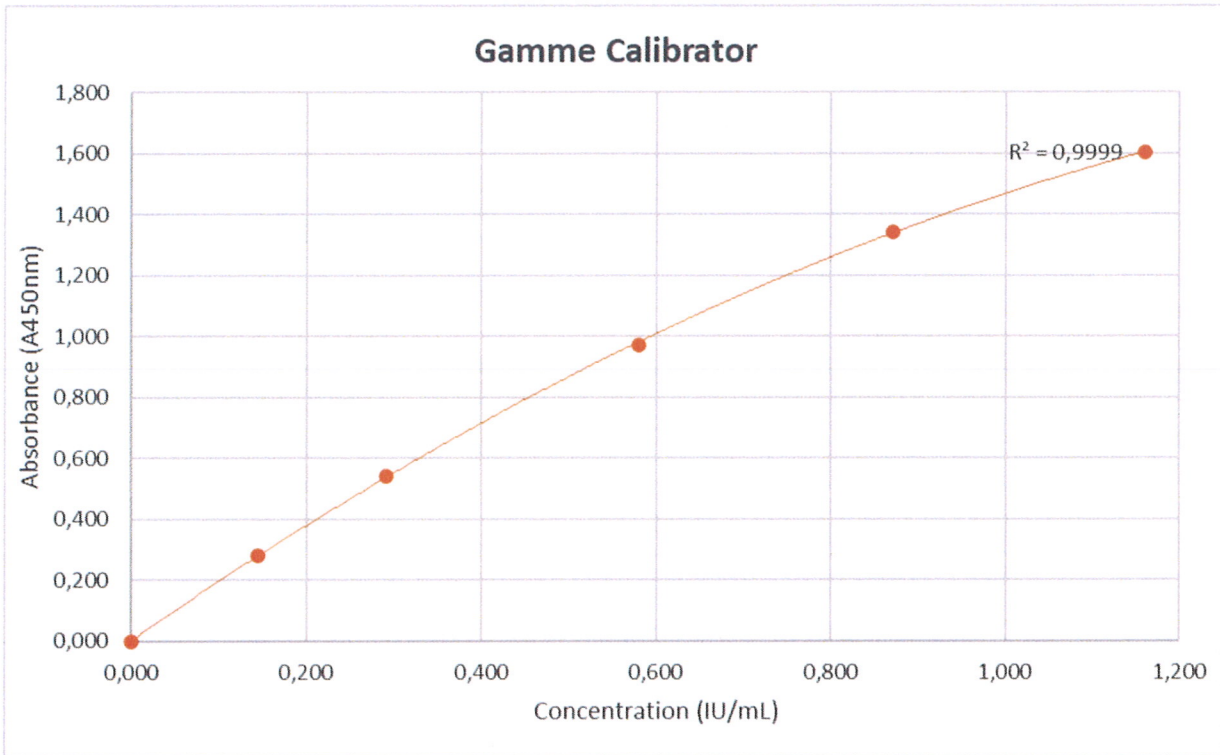
**Analytical results:**

Control parameter	Results	Specifications	Conclusion
Kit performances (20°C +/- 1°C)	A450 (1.0 IU/ml) = 1.47	1.20 – 2.50	Passed
	ΔA450 (1.0-0.50 IU/ml) = 0.75	> 0.40	Passed
	Blank (A450) = 0.051	< 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> = 0.9999	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 = 7.49 à 20.5°C	pH 7.20 - 7.80	Passed

# 5 5-Diagnostics

Immuno-Conjugate diluent	pH = 7.48 à 21°C	pH 7.20 -7.80	Passed
Wash solution (20x)	pH = 7.40 à 21.5°C (diluted)	pH 7.00 - 8.00	Passed
Stop solution (sulfuric acid) tested tenfold diluted	pH = 1.30	pH 1.00 +/- 0.50	Passed

**Calibration curve:**



**Waivers:**

**Conclusions:**

Currently tested lot	Specification
240611-10	Passed

The ADAMTS-13 Elisa kit **lot 240611-10** is compliant with expected specifications and released.

Date: June 25<sup>th</sup>, 2024

Approved by: Barbara Stix 