

Certificate of Analysis

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

Reference: 5D-55501

Lot: 260219-20

Expiration date: 2028-01-31

Store at 2-8°C

Kit composition:

Component	Code Id	Lot	Expiration date	N vials/kit
EIA Dilution Buffer	SD	250903-20	03/09/2028	2
EIA Washing Buffer	WS	250904-10	04/09/2028	1
EIA Stop Solution	SA	250603-40	03/06/2028	1
Immuno-Conjugate Diluent	ICD	250903-10	03/09/2028	1
Micro ELISA Plate	COAT	250909-10	09/09/2028	1
Calibrator	CAL	250606-10	06/06/2028	2
Plasma Control High	C1	250606-20		2
Plasma Control Low	C2	250606-30		2
Immuno-Conjugate	IC	260216-10	16/02/2028	1
TMB/H2O2 Peroxidase Substrate	SU	240101D01	31/01/2028	1

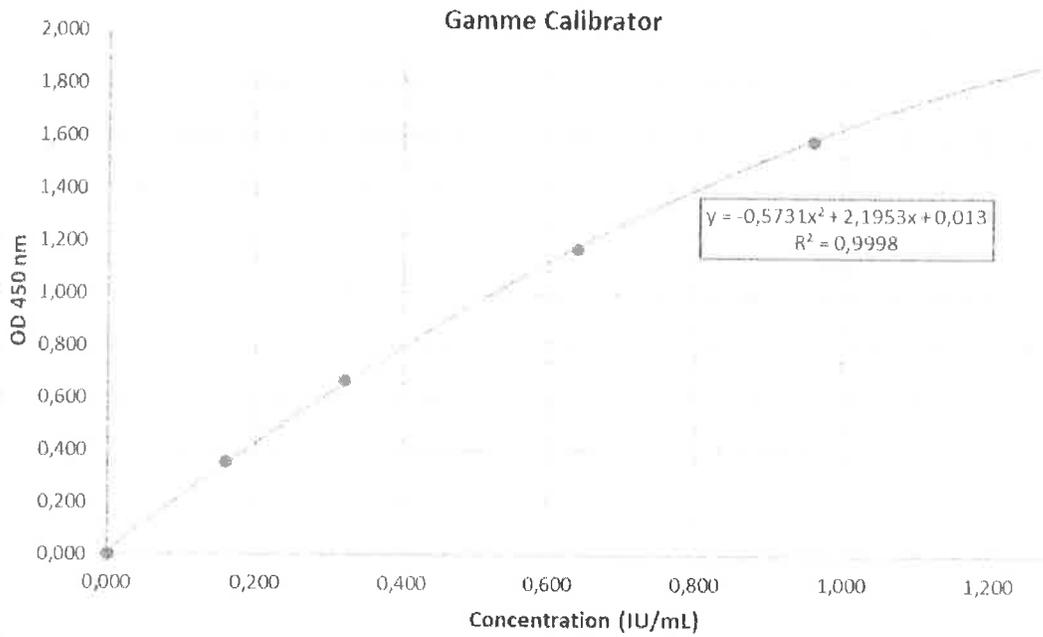
Analytical results:

Control parameter	Results	Specifications	Conclusion
Kit performances (20°C +/- 1°C)	A450 (1.0 IU/ml) = 1.64	1.20 – 2.50	Passed
	ΔA450 (1.0-0.50 IU/ml) = 0.67	> 0.40	Passed
	Blank (A450) = 0.064	< 0.15	Passed
	Intra assay CV: C1 4.17 % C2 6.40 %	< 8%	Passed
	Inter assay CV: C1 4.10 % C2 6.60 %	< 10%	Passed
Calibration curve linearity	R ² = 0.9998	R ² ≥ 0.98	Passed
ADAMTS13 calibrator IU/ml (Ref: WHO International Standard)	C = 1.28	0.80 – 1.40	Passed
ADAMTS13 control C1 (IU/ml) Mean, Acceptance range (+/-15%)	Mean C1 = 0.92 IU/ml Range: 0.79-1.05	0.70 – 1.00 +/- 15%	Passed
ADAMTS13 control C2 (IU/ml) Mean, Acceptance range (+/- 20%)	Mean C2 = 0.48 IU/ml Range: 0.39-0.57	0.25 – 0.50 +/- 20%	Passed

5 5-Diagnostics

TMB-H2O2 substrate	Clear solution	Clear solution	Passed
Dilution buffer	pH = 7.50	pH 7.20 - 7.80	Passed
Immuno-Conjugate diluent	pH = 7.50	pH 7.20 - 7.80	Passed
Wash solution (20x)	pH = 7.42 (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:



Waivers:

Conclusions:

Currently tested lot	Specification
260219-20	Passed

The ADAMTS-13 Elisa kit lot **260219-20** is compliant with expected specifications and released.

Date: 2026-02-19

Approved by:

R. KOLMER