

Certificate of Analysis

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

Reference: 5D-55501

Lot: 250515-20

Expiration date: 2025-11-26

Store at 2-8°C

Kit composition:

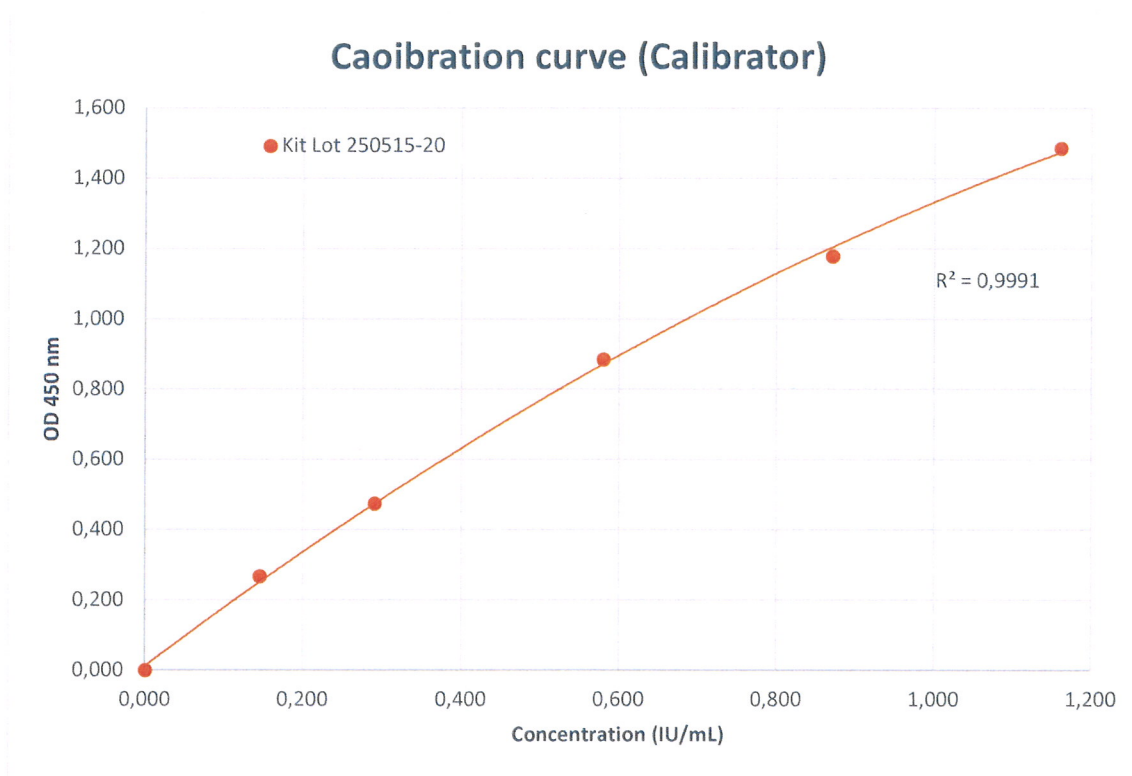
Component	Code Id	Lot	Expiration date	N vials/kit
EIA Dilution Buffer	SD	230130-10	30/01/2026	2
EIA Washing Buffer	WS	230629-10	29/06/2026	1
EIA Stop Solution	SA	240328-10	28/03/2027	1
Immuno-Conjugate Diluent	ICD	230627-10	27/06/2026	1
Micro ELISA Plate	COAT	240610-10	24/06/2027	1
Calibrator	CAL	211126-11	26/11/2025	2
Plasma Control High	C1	211130-11	30/11/2025	2
Plasma Control Low	C2	211130-21	30/11/2025	2
Immuno-Conjugate	IC	240610-20	10/06/2026	1
TMB/H2O2 Peroxidase Substrate	SU	220201D05	28/02/2026	1

Analytical results:

Control parameter	Results	Specifications	Conclusion
Kit performances (20°C +/- 1°C)	A450 (1.0 IU/ml) = 1.38	1.20 – 2.50	Passed
	Δ A450 (1.0-0.50 IU/ml) = 0.60	> 0.40	Passed
	Blank (A450) = 0.05	< 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 ² = 0.9991	R ² ≥ 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-H2O2 substrate	Clear solution	Clear solution	Passed

Dilution buffer	pH = 7.49 à 20.5°C	pH 7.20 - 7.80	Passed
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
250515-20	Passed

The ADAMTS-13 Elisa kit **lot 250515-20** is compliant with expected specifications and released.

Date: 28.05.2025

Approved by:

M. Stenier