

# CERTIFICATE OF ANALYSIS

## TECHNOZYM ADAMTS13 Activity ELISA Kit



Temp.: TP0327.07

Attachment 03      DQRU00.11

RU5AC00.02

REF	5450701-US
LOT	RU5AC00.02
	2027-02-28

Content	volume	Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	535	2027-02-28
1x	30mL	ADAMTS-13 Activity Reaction Buffer	535	2027-02-28
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	535	2027-02-28
1x	12mL	ADAMTS-13 Activity Color Reagent	535	2027-02-28
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	535	2027-02-28
1x	12mL	ADAMTS-13 Activity Stop Solution	535	2027-02-28
1x	n.a.	ADAMTS-13 Activity Plate 96T.	535	2027-02-28
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT51C0	2027-03-31
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY51C0	2027-03-31
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT51C0	2027-03-31

Analytical Procedures		Requirement	Result	
visual inspection	Content	according to packaging SOP	confirmed	OK
	Vial label	according to packaging SOP	confirmed	OK
	Vial barcode	according to packaging SOP	confirmed	OK
	Box label	according to packaging SOP	confirmed	OK
	Box barcode	according to packaging SOP	confirmed	OK
	Package insert	present	confirmed	OK
	Batch table	present	confirmed	OK
Verwendbarkeit Usability	<b>deltaOD Cal1-Cal6</b>	≥ 0.7	1.7	OK
Recovery of controls	<b>ADAMTS-13 Activity High Control</b> LOT RUY51C0	0.70 - 1.16 IU/mL	0.93 IU/mL	OK
	<b>ADAMTS-13 Activity Low Control</b> LOT RUZ51C0	0.15 - 0.35 IU/mL	0.27 IU/mL	OK

Prepared by

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23. OKT. 2025

Date

Approved by

Fikret NASUFI *Fikret Nasufi*

23. OKT. 2025

Date