

CERTIFICATE OF ANALYSIS
TECHNOZYM ADAMTS13 Activity ELISA Kit



Temp.: F0327.07

Attachment 03 DQRU00.10

RU48C00.02

REF 5450701-US
 LOT RU48C00.02
 2026-01-31

Content	volume	Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	430	2026-01-31
1x	30mL	ADAMTS-13 Activity Reaction Buffer	430	2026-01-31
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	430	2026-01-31
1x	12mL	ADAMTS-13 Activity Color Reagent	430	2026-01-31
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	430	2026-01-31
1x	12mL	ADAMTS-13 Activity Stop Solution	430	2026-01-31
1x	n.a.	ADAMTS-13 Activity Plate 96T.	430	2026-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT41C0	2026-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT41C0	2026-02-28
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT41C0	2026-02-28
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT41C0	2026-02-28
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT41C0	2026-02-28
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY41C0	2026-02-28
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ41C0	2026-02-28
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT41C0	2026-02-28

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	deltaOD Cal1-Cal6	≥ 0.7	1.5
Recovery of controls	ADAMTS-13 Activity High Control LOT RUY41C0	0.71 - 1.19 IU/mL	0.86 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ41C0	0.15 - 0.35 IU/mL	0.17 IU/mL	OK

Prepared by

Fikret NASUFI Fikret Nasufi

16. AUG. 2024

Date

Approved by

Lucas HOLOWCZ

16. AUG. 2024

Date