

CERTIFICATE OF ANALYSIS
TECHNOZYM ADAMTS13 Activity CAL Set



Temp.: TFO327.07

Attachment 06 DQxUT0.05
8UT42C0.02

REF 5450761-RUO
LOT 8UT42C0.02
⌚ 2026-07-31

Content	Volume	Reagent	LOT	⌚
1x	0.5 mL	ADAMTS13 Activity CAL 1	1UT42C0	2026-08-31
1x	0.5 mL	ADAMTS13 Activity CAL 2	2UT42C0	2026-08-31
1x	0.5 mL	ADAMTS13 Activity CAL 3	3UT42C0	2026-07-31
1x	0.5 mL	ADAMTS13 Activity CAL 4	4UT42C0	2026-08-31
1x	0.5 mL	ADAMTS13 Activity CAL 5	5UT42C0	2026-08-31
1x	0.5 mL	ADAMTS13 Activity CAL 6	6UT42C0	2026-08-31

Analytical Procedures		Requirement		Result	
visual inspection	Content	according to packaging SOP		confirmed	OK
	Vial label	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
Usability	delta OD Cal 1 - Cal 6	≥ 0.7		1.9	OK
Recovery of controls	ADAMTS13 Activity CONT H LOT RUY42C0	0.71	- 1.19 IU/mL	1.00 IU/mL	OK
	ADAMTS13 Activity CONT L LOT RUZ42C0	0.17	- 0.39 IU/mL	0.29 IU/mL	OK

Prepared by Fikret NASUFI Fikret Nasufi

22. OKT. 2024
Date

Approved by LUCASZ HOLEWICZ

22. OKT. 2024
Date