

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQRP0.02
		Att.17
		RP52C0S.02

TECHNOZYM ADAMTS13 INH ELISA 48 T.

REF	5450451-RUO
LOT	RP52C0S.02
	2026-07-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	-	ADAMTS13 INH plate 48 T.	RPS51CS	2027-01-31
1x	0.3 mL	ADAMTS13 INH POX	RPV42C0	2026-10-31
1x	0.5 mL	ADAMTS13 INH Calibrator 1	1PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Calibrator 2	2PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Calibrator 3	3PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Calibrator 4	4PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Calibrator 5	5PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH High Control	RPY41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Low Control	RPZ41C0	2026-09-30
1x	12 mL	Stop Solution	RKK42C0	2026-09-30
1x	12 mL	TMB Substrate	RKN42C0	2026-08-31
1x	80 mL	Wash buffer concentrate	RNA41C0	2026-08-31
1x	90 mL	Incubation buffer	RNB41C0	2026-07-31

Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result	
visuelle Kontrolle 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
Verwendbarkeit Usability	Kurvensteigung Slope	≥ 0.7	1.5	OK
	ADAMTS13 INH High Control LOT RPY41C0	41.54 - 69.24 U/mL	55.47 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ41C0	10.31 - 24.07 U/mL	19.52 U/mL	OK

Durchgeföhrt von Prepared by	<u>Fikret NASUFI Fikret Nasufi</u>	<u>0 5. FEB. 2025</u> Datum / Date:
Freigabe von Approved by	<u>Ljiljana HOLJEVICZ</u>	<u>0 5. FEB. 2025</u> Datum / Date: