

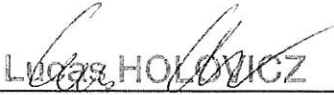
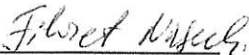
	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQRP0.02 Att.17 RP48C0S.02
	TECHNOZYM ADAMTS13 INH ELISA 48 T.	
	REF 5450451-RUO LOT RP48C0S.02  2025-11-30	

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	-	ADAMTS13 INH plate 48 T.	RPS42CS	2026-04-30
1x	0.3 mL	ADAMTS13 INH POX	RPV41C0	2026-04-30
1x	0.5 mL	ADAMTS13 INH Calibrator 1	1PT31C0	2025-11-30
1x	0.5 mL	ADAMTS13 INH Calibrator 2	2PT31C0	2025-11-30
1x	0.5 mL	ADAMTS13 INH Calibrator 3	3PT31C0	2025-11-30
1x	0.5 mL	ADAMTS13 INH Calibrator 4	4PT31C0	2025-11-30
1x	0.5 mL	ADAMTS13 INH Calibrator 5	5PT31C0	2025-11-30
1x	0.5 mL	ADAMTS13 INH High Control	RPY31C0	2025-11-30
1x	0.5 mL	ADAMTS13 INH Low Control	RPZ31C0	2025-11-30
1x	12 mL	Stop Solution	RKK41C0	2026-04-30
1x	12 mL	TMB Substrate	RKN41C0	2026-03-31
1x	80 mL	Wash buffer concentrate	RNA33C0	2025-12-31
1x	90 mL	Incubation buffer	RNB33C0	2025-12-31

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	1.8	OK
	ADAMTS13 INH High Control LOT RPY31C0	42.53 - 70.88 U/mL	51.57 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ31C0	13.17 - 30.73 U/mL	19.84 U/mL	OK

Durchgeführt von Prepared by		10. JULI 2024 Datum / Date:
Freigabe von Approved by	Fikret NASUFI 	10. JULI 2024 Datum / Date: