

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQRP0.02
		Att. 17
		RP54C0S.02

TECHNOZYM ADAMTS13 INH ELISA 48 T.

REF	5450451-RUO
LOT	RP54C0S.02
	2026-10-31

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	1PT51C0	2027-04-30
1x	0.5 mL	ADAMTS13 INH Calibrator 2	2PT51C0	2027-04-30
1x	0.5 mL	ADAMTS13 INH Calibrator 3	3PT51C0	2027-05-31
1x	0.5 mL	ADAMTS13 INH Calibrator 4	4PT51C0	2027-05-31
1x	0.5 mL	ADAMTS13 INH Calibrator 5	5PT51C0	2027-05-31
1x	0.5 mL	ADAMTS13 INH High Control	RPY51C0	2027-05-31
1x	0.5 mL	ADAMTS13 INH Low Control	RPZ51C0	2027-05-31
1x	12 mL	Stop Solution	RKK51C0	2027-02-28
1x	12 mL	TMB Substrate	RKN51C0	2027-01-31
1x	80 mL	Wash buffer concentrate	RNA42C0	2026-12-31
1x	90 mL	Incubation buffer	RNB42C0	2026-10-31

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	1.3	OK
	ADAMTS13 INH High Control LOT RPY51C0	41.89 - 69.81 U/mL	59.72 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ51C0	10.81 - 25.23 U/mL	16.64 U/mL	OK

Durchgeföhrt von
Prepared by


LUCAS HOLOVICZ

02. JULI 2025
Datum / Date:

Freigabe von
Approved by


MIKROT NASUFI

03. JULI 2025
Datum / Date: