



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRP0.02
Att.16
RP45C00.02

TECHNOZYM ADAMTS13 INH ELISA 96 T.

REF	5450401-RUO
LOT	RP45C00.02
	2025-11-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	-	ADAMTS13 INH plate 96 T.	RPS43C0	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 1.5 OK
	ADAMTS13 INH High Control LOT RPY31C0	42.53 - 70.88 U/mL 48.70 U/mL OK
	ADAMTS13 INH Low Control LOT RPZ31C0	13.17 - 30.73 U/mL 18.93 U/mL OK

Durchgeführt von
Prepared by

Nikret NASUFI
Nikret NASUFI

14. MAI 2024

Datum / Date:

Freigabe von
Approved by

Maylis HAUSCHER
Maylis HAUSCHER

14. MAI 2024

Datum / Date: