



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRP0.02

Att. 18

6PT42C0.02

TECHNOZYM ADAMTS13 INH Calibrator Set 5x0.5 mL

REF	5450461-RUO
LOT	6PT42C0.02
	2026-09-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
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

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
Verwendung Usability	Kurvensteigung Slope	≥ 0.7	0.9	OK
	ADAMTS13 INH High Control LOT RPY41C0	41.54 - 69.24 U/mL	62.55 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ41C0	10.31 - 24.07 U/mL	16.35 U/mL	OK

Durchgeführt von
Prepared by

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09. OKT. 2024

Datum / Date:

Freigabe von
Approved by

Maylis FAUSCHER

09. OKT. 2024

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