



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRP0.02

Att.18

6PT41C0.02

TECHNOZYM ADAMTS13 INH Calibrator Set 5x0.5 mL

REF 5450461-RUO
LOT 6PT41C0.02
2025-11-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	2025-11-30
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

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	1.6	OK
	ADAMTS13 INH High Control LOT RPY31C0	42.53 - 70.88 U/mL	59.43 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ31C0	13.17 - 30.73 U/mL	22.10 U/mL	OK

Durchgeführt von
Prepared by

Fikret NASUFI Fikret Nasufi

16. FEB. 2024

Datum / Date:

Freigabe von
Approved by

Lucas HOLZNER

16. FEB. 2024

Datum / Date: