

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQxUT0.03
		Att.06
		8UT02C0.02

TECHNOZYM® ADAMTS13 Activity CAL Set 6x0.5 mL

REF	5450761
LOT	8UT02C0.02
	2022-04-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	0.5mL	ADAMTS13 Activity Calibrator 1	1UT01C0	2022-04-30
1x	0.5mL	ADAMTS13 Activity Calibrator 2	2UT01C0	2022-04-30
1x	0.5mL	ADAMTS13 Activity Calibrator 3	3UT01C0	2022-04-30
1x	0.5mL	ADAMTS13 Activity Calibrator 4	4UT01C0	2022-04-30
1x	0.5mL	ADAMTS13 Activity Calibrator 5	5UT01C0	2022-04-30
1x	0.5mL	ADAMTS13 Activity Calibrator 6	6UT01C0	2022-04-30

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
Verwendbarkeit Usability	deltaOD Cal1-Cal6	≥ 0.7	2.1	OK
Kontrollwiederfindung Recovery of controls	ADAMTS13 Activity High Control LOT RUY01C0	0.52 - 0.86 IU/mL	0.68 IU/mL	OK
	ADAMTS13 Activity Low Control LOT RUZ01C0	0.13 - 0.29 IU/mL	0.22 IU/mL	OK

Durchgeführt von
Prepared by

Michael KAFKA 

09. DEZ. 2020

Datum / Date:

Freigabe von
Approved by

Fikret NASUFI 

09. DEZ. 2020

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