

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQxUT0.03
		Att.12
		7UT11C0.02

TECHNOZYM® ADAMTS13 Activity CON Set 2x0.5 mL

REF	5450763-RUO
LOT	7UT11C0.02
	2023-01-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	0.5mL	ADAMTS13 Activity High Control	RUY02C0	2023-01-31
1x	0.5mL	ADAMTS13 Activity Low Control	RUZ02C0	2023-01-31

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
Kontrollwiederfindung Recovery of controls	ADAMTS13 Activity High Control LOT RUY02C0	0.53 - 0.89 IU/mL	0.72 IU/mL	OK
	ADAMTS13 Activity Low Control LOT RUZ02C0	0.13 - 0.29 IU/mL	0.23 IU/mL	OK

Durchgeführt von
Prepared by

Michael KAFKA 

22. MRZ. 2021

Datum / Date:

Freigabe von
Approved by

Fikret NASUFI 

22. MRZ. 2021

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