



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQxUT0.02

Att.20

8UT92B0.02

## TECHNOZYM® ADAMTS-13 Activity Calibrator Set 6 x 0.5 mL

REF	5450761
LOT	8UT92B0.02
	2021-01-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	0.5mL	ADAMTS-13 Activity Calibrator 1	1UT91B0	2021-01-31
1x	0.5mL	ADAMTS-13 Activity Calibrator 2	2UT91B0	2021-01-31
1x	0.5mL	ADAMTS-13 Activity Calibrator 3	3UT91B0	2021-01-31
1x	0.5mL	ADAMTS-13 Activity Calibrator 4	4UT91B0	2021-01-31
1x	0.5mL	ADAMTS-13 Activity Calibrator 5	5UT91B0	2021-01-31
1x	0.5mL	ADAMTS-13 Activity Calibrator 6	6UT91B0	2021-01-31

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
	Vial barcode	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	1.4   OK
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RUY91B0	0.50 - 0.84 IU/mL   0.78 IU/mL   OK
	ADAMTS-13 Activity Low Control LOT RUZ91B0	0.13 - 0.29 IU/mL   0.25 IU/mL   OK

Durchgeführt von  
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17. OCT. 2019

Datum / Date:

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Approved by

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17. OKT. 2019

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