



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQxUT0.01

Alt.20

8UT72B0.02

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

REF	5450761
LOT	8UT72B0.02
	2019-06-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	0.5mL	ADAMTS-13 Activity Calibrator 1	1UT71B0	2019-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 2	2UT71B0	2019-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 3	3UT71B0	2019-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 4	4UT71B0	2019-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 5	5UT71B0	2019-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 6	6UT71B0	2019-06-30

Analytische Verfahren Analytical Procedures	Anforderung Requirement	Ergebnis Result
visuelle Kontrolle visual inspection	Content	according to packaging SOP
	Vial label	confirmed OK
	Vial barcode	confirmed OK
	Box label	confirmed OK
	Box barcode	confirmed OK
	Package insert	confirmed OK
	Batch table	confirmed OK
Verwendbarkeit Usability	deltaOD Cal1-Cal6 ≥ 0.7	1.5 OK
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RU71B00 0.59 - 0.98 IU/mL	0.92 IU/mL OK
	ADAMTS-13 Activity Low Control LOT RUZ71B00 0.13 - 0.31 IU/mL	0.26 IU/mL OK

Durchgeführt von
Prepared by

Fikrot NASUFI *Fikrot Nasufi*

26. FEB. 2018

Datum / Date:

Freigabe von
Approved by

Michael KAFKA *[Signature]*

26. FEB. 2018

Datum / Date: