



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	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	1.5	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

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