



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRU00.04

Att.05

RU93B00.02

## TECHNOZYM® ADAMTS-13 Activity ELISA 96T.

REF	5450701
LOT	RU93B00.02
	2020-09-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	910	2020-09-30
1x	30mL	ADAMTS-13 Activity Reaction Buffer	910	2020-09-30
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	910	2020-09-30
1x	12mL	ADAMTS-13 Activity Color Reagent	910	2020-09-30
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	910	2020-09-30
1x	12mL	ADAMTS-13 Activity Stop Solution	910	2020-09-30
1x	n.a.	ADAMTS-13 Activity Plate 96T.	910	2020-09-30
1x	n.a.	ADAMTS-13 Activity sample dilution MTP	910	2020-09-30
3x	n.a.	ADAMTS-13 Activity Plate Seal	910	2020-09-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT91B0	2021-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT91B0	2021-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT91B0	2021-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT91B0	2021-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT91B0	2021-01-31
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY91B0	2021-01-31
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ91B0	2021-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT91B0	2021-01-31

Analytische Verfahren Analytical Procedures	Anforderung Requirement	Ergebnis Result
visuelle Kontrolle visual inspection	Content	according to packaging SOP
	Vial label	confirmed
	Vial barcode	OK
	Box label	confirmed
	Box barcode	OK
	Package insert	confirmed
	Batch table	OK
Verwendbarkeit Usability	deltaOD Cal1-Cal6 ≥ 0.7	1.6 OK
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RUY91B0	0.50 - 0.84 IU/mL 0.75 IU/mL OK
	ADAMTS-13 Activity Low Control LOT RUZ91B0	0.13 - 0.29 IU/mL 0.25 IU/mL OK

	<b>ANALYSENZERTIFIKAT</b> <b>CERTIFICATE OF ANALYSIS</b>	DQRU00.04 Att.05  RU93B00.02
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Durchgeföhrt von  
Prepared by Fikret NASUFI *Fikret Nasufi*

25. MRZ. 2019  
Datum / Date:

Freigabe von  
Approved by Michael KAFKA *[Signature]*

25. MRZ. 2019  
Datum / Date: