



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRU00.06

Att.08

RU0FC00.01

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

REF	5450701-RUO
LOT	RU0FC00.01
	2021-11-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	020	2021-11-30
1x	30mL	ADAMTS-13 Activity Reaction Buffer	020	2021-11-30
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	020	2021-11-30
1x	12mL	ADAMTS-13 Activity Color Reagent	020	2021-11-30
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	020	2021-11-30
1x	12mL	ADAMTS-13 Activity Stop Solution	020	2021-11-30
1x	n.a.	ADAMTS-13 Activity Plate 96T.	020	2021-11-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT01C0	2022-04-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT01C0	2022-04-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT01C0	2022-04-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT01C0	2022-04-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT01C0	2022-04-30
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY01C0	2022-04-30
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ01C0	2022-04-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT01C0	2022-04-30

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	≥ 0.7
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RUY01C0	0.52 - 0.86 IU/mL   0.76 IU/mL   OK
	ADAMTS-13 Activity Low Control LOT RUZ01C0	0.13 - 0.29 IU/mL   0.21 IU/mL   OK



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Durchgeführt von

Prepared by

Fikret NASUFI *Fikret Nasufi*

12. JUNI 2020

Datum / Date:

Freigabe von

Approved by

Michael KAFKA *[Signature]*

15. JUNI 2020

Datum / Date: