


	ANALYSENZERTIFIKAT	DQRU00.06
	CERTIFICATE OF ANALYSIS	Att.08
		RU0HC00.01

TECHNOZYM® ADAMTS-13 Activity ELISA 96T.

REF	5450701-RUO
LOT	RU0HC00.01
	2021-12-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	025	2021-12-31
1x	30mL	ADAMTS-13 Activity Reaction Buffer	025	2021-12-31
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	025	2021-12-31
1x	12mL	ADAMTS-13 Activity Color Reagent	025	2021-12-31
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	025	2021-12-31
1x	12mL	ADAMTS-13 Activity Stop Solution	025	2021-12-31
1x	n.a.	ADAMTS-13 Activity Plate 96T.	025	2021-12-31
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	deltaOD Cal1-Cal6	≥ 0.7	2.0	OK
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RUY01C0	0.52 - 0.86 IU/mL	0.66 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ01C0	0.13 - 0.29 IU/mL	0.25 IU/mL	OK

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Durchgeföhrt von
Prepared by

Fikret NASUFI *Fikret Nasufi*

27. JULI 2020

Datum / Date:

Freigabe von
Approved by

Michael KAFKA *[Signature]*

27. JULI 2020

Datum / Date: