



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRU00.06

Att.08

RU1JC00.02

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

REF	5450701-RUO
LOT	RU1JC00.02
	2023-02-28

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	135	2023-02-28
1x	30mL	ADAMTS-13 Activity Reaction Buffer	135	2023-02-28
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	135	2023-02-28
1x	12mL	ADAMTS-13 Activity Color Reagent	135	2023-02-28
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	135	2023-02-28
1x	12mL	ADAMTS-13 Activity Stop Solution	135	2023-02-28
1x	n.a.	ADAMTS-13 Activity Plate 96T.	135	2023-02-28
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT12C0	2023-07-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT12C0	2023-07-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT12C0	2023-07-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT12C0	2023-07-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT12C0	2023-07-31
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY12C0	2023-07-31
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ12C0	2023-07-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT12C0	2023-07-31

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	<b>deltaOD Cal1-Cal6</b> ≥    0.7	1.6    OK
Kontrollwiederfindung Recovery of controls	<b>ADAMTS-13 Activity High Control</b> LOT RUY12C0	0.56    -    0.94 IU/mL    0.65 IU/mL    OK
	<b>ADAMTS-13 Activity Low Control</b> LOT RUZ12C0	0.14    -    0.32 IU/mL    0.27 IU/mL    OK



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Durchgeföhrt von  
Prepared by

Michael KAFKA 

09. SEP. 2021

Datum / Date:

Freigabe von  
Approved by

Fikret NASUFI 

09. SEP. 2021

Datum / Date: