



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRU00.06

Att.08

RU02C00.01

TECHNOZYM® ADAMTS-13 Activity ELISA 96T.


REF 5450701-RUO

LOT RU02C00.01

2021-05-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	950	2021-05-31
1x	30mL	ADAMTS-13 Activity Reaction Buffer	950	2021-05-31
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	950	2021-05-31
1x	12mL	ADAMTS-13 Activity Color Reagent	950	2021-05-31
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	950	2021-05-31
1x	12mL	ADAMTS-13 Activity Stop Solution	950	2021-05-31
1x	n.a.	ADAMTS-13 Activity Plate 96T.	950	2021-05-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT92B0	2021-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT92B0	2021-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT92B0	2021-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT92B0	2021-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT92B0	2021-06-30
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY92B0	2021-06-30
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ92B0	2021-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT92B0	2021-06-30

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	1.9
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RUY92B0	0.49 - 0.81 IU/mL	0.70 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ92B0	0.14 - 0.32 IU/mL	0.24 IU/mL	OK

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Durchgeföhrt von
Prepared by

Michael KAFKA 

23. JAN. 2020
Datum / Date:

Freigabe von
Approved by

Fikret NASUFI 

23. JAN. 2020
Datum / Date: