



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRU00.06

Att.08


RU1HC00.02

TECHNOZYM® ADAMTS-13 Activity ELISA 96T.

REF	5450701-RUO
LOT	RU1HC00.02
	2023-01-31

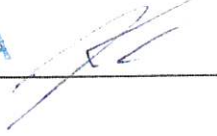
Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	130	2023-01-31
1x	30mL	ADAMTS-13 Activity Reaction Buffer	130	2023-01-31
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	130	2023-01-31
1x	12mL	ADAMTS-13 Activity Color Reagent	130	2023-01-31
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	130	2023-01-31
1x	12mL	ADAMTS-13 Activity Stop Solution	130	2023-01-31
1x	n.a.	ADAMTS-13 Activity Plate 96T.	130	2023-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT02C0	2023-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT02C0	2023-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT02C0	2023-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT02C0	2023-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT02C0	2023-01-31
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY02C0	2023-01-31
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ02C0	2023-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT02C0	2023-01-31

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	deltaOD Cal1-Cal6	≥ 0.7	1.8
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RUY02C0	0.53 - 0.89 IU/mL	0.69 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ02C0	0.13 - 0.29 IU/mL	0.21 IU/mL	OK

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Durchgeföhrt von
Prepared by

Michael KAFKA



16. AUG. 2021

Datum / Date:

Freigabe von
Approved by

Fikret NASUFI



17. AUG. 2021

Datum / Date: