



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRU00.04

Att.05

RU83B00.01

TECHNOZYM® ADAMTS-13 Activity ELISA 96T.

REF	5450701
LOT	RU83B00.01
	2019-06-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	815	2019-10-31
1x	30mL	ADAMTS-13 Activity Reaction Buffer	815	2019-10-31
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	815	2019-10-31
1x	12mL	ADAMTS-13 Activity Color Reagent	815	2019-10-31
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	815	2019-10-31
1x	12mL	ADAMTS-13 Activity Stop Solution	815	2019-10-31
1x	n.a.	ADAMTS-13 Activity Plate 96T.	815	2019-10-31
1x	n.a.	ADAMTS-13 Activity sample dilution MTP	815	2019-10-31
3x	n.a.	ADAMTS-13 Activity Plate Seal	815	2019-10-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT71B0	2019-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT71B0	2019-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT71B0	2019-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT71B0	2019-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT71B0	2019-06-30
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY71B0	2019-06-30
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ71B0	2019-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT71B0	2019-06-30

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	1.4	OK
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RUY71B0	0.59 - 0.98 IU/mL	0.87 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ71B0	0.13 - 0.31 IU/mL	0.25 IU/mL	OK



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Durchgeföhrt von

Prepared by

Fikret NASUFI *Fikret Nasufi*

22. MAI 2018

Datum / Date:

Freigabe von

Approved by

Eva Maria HAGER *Eva Maria Hager*

22. MAI 2018

Datum / Date: