



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRU00.04

Att.05

RU87B00.02

TECHNOZYM® ADAMTS-13 Activity ELISA 96T.

REF	5450701
LOT	RU87B00.02
	2020-01-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	830	2020-01-31
1x	30mL	ADAMTS-13 Activity Reaction Buffer	830	2020-01-31
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	830	2020-01-31
1x	12mL	ADAMTS-13 Activity Color Reagent	830	2020-01-31
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	830	2020-01-31
1x	12mL	ADAMTS-13 Activity Stop Solution	830	2020-01-31
1x	n.a.	ADAMTS-13 Activity Plate 96T.	830	2020-01-31
1x	n.a.	ADAMTS-13 Activity sample dilution MTP	830	2020-01-31
3x	n.a.	ADAMTS-13 Activity Plate Seal	830	2020-01-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT81B0	2020-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT81B0	2020-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT82B0	2020-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT81B0	2020-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT81B0	2020-06-30
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY81B0	2020-06-30
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ81B0	2020-06-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT81B0	2020-06-30

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	1.5	OK
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RUY81B0	0.53 - 0.89 IU/mL	0.85 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ81B0	0.13 - 0.29 IU/mL	0.26 IU/mL	OK



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Durchgeföhrt von
Prepared by

Fikret NASUFI *Fikret Nasufi*

04. SEP. 2018

Datum / Date:

Freigabe von
Approved by

Michael KAFKA *[Signature]*

04. SEP. 2018

Datum / Date: