



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRR00.02

Att.04

RR03C00.01

TECHNOZYM ADAMTS-13 Antigen ELISA 96T.

REF	5450601
LOT	RR03C00.01
	2021-08-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	⌚
1x	-	HFP: RS ADAMTS-13 Ag ELISA Platte 96T.	RRS01C0	2022-04-30
1x	0.3 mL	HFP: QV ADAMTS-13 Conjugate	RQV01C0	2022-04-30
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 1	RNA03C0	2022-05-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 2	RNB93B0	2021-10-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 3	RKN01C0	2022-01-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 4	RKK01C0	2022-01-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 5	1RT91B0	2021-08-31
1x	0.5 mL	HFP: RY ADAMTS-13 Antigen High Control	2RT91B0	2021-08-31
1x	0.5 mL	HFP: RZ ADAMTS-13 Antigen Low Control	3RT91B0	2021-08-31
1x	80 mL	HFP: NA wash buffer + thimerosal	4RT91B0	2021-08-31
1x	90 mL	HFP: NB Incubation buffer	5RT91B0	2021-08-31
1x	12 mL	HFP: KK Stop solution for TMB	RRY91B0	2021-08-31
1x	12 mL	HFP: KN TMB Substrate	RRZ91B0	2021-08-31

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
	Box label	according to packaging SOP	confirmed	OK
	Package insert	present	confirmed	OK
	Batch table	present	confirmed	OK
Verwendbarkeit Usability	\geq 0.7	1.1		OK
Kontrollwiederfindung Recovery of controls	High Control LOT RRY91B0	0.47 - 0.79 IU/mL	0.64 IU/mL	OK
	Low Control LOT RRZ91B0	0.12 - 0.28 IU/mL	0.19 IU/mL	OK



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Durchgeföhrt von
Prepared by

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29. Juli 2020

Datum / Date:

Freigabe von
Approved by

Christoph ENNE

29. Juli 2020

Datum / Date: