



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRO00.02

Att.13

RQ01C00.01

TECHNOZYM ADAMTS13 ELISA 2x48T.

REF	5450501
LOT	RQ01C00.01
	2021-06-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	0.3 mL	HFP: QV ADAMTS-13 Conjugate	RQV92B0	2022-01-31
2x	n.a.	HFP: QS ADAMTS-13 Platte 48T.	RQS91B0	2021-06-30
2x	3 mL	HFP: QW ADAMTS-13 Activity Substrate	RQW91B0	2021-12-31
1x	6 mL	HFP: QL ADAMTS-13 Antigen Substrate	RQX91B0	2022-01-31
1x	0.7 mL	HFP: QL ADAMTS-13 Antigen Stable Peroxide	RQL91B0	2022-01-31
1x	6 mL	HFP: QL ADAMTS-13 Antigen Stop Solution	RQK91B0	2022-01-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 1	1RT91B0	2021-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 2	2RT91B0	2021-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 3	3RT91B0	2021-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 4	4RT91B0	2021-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 5	5RT91B0	2021-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen High Control	RRY91B0	2021-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Low Control	RRZ91B0	2021-08-31
1x	80 mL	HFP: NA wash buffer + thimerosal	RNA93B0	2021-09-30
1x	90 mL	HFP: NB Incubation buffer	RNB93B0	2021-10-31

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
	Box barcode	according to packaging SOP confirmed OK
	Package insert	present confirmed OK
	Batch table	present confirmed OK
Funktion Function	Δ RFU/min Activity	\geq 200.0 RFU 420 RFU OK
	High Control (Activity) LOT RRY91B0	0.55 - 0.91 IU/mL 0.68 IU/mL OK
	Low Control (Activity) LOT RRZ91B0	0.12 - 0.28 IU/mL 0.19 IU/mL OK
	Δ RFU/min Antigen	\geq 200.0 RFU 299 RFU OK
	High Control (Antigen) LOT RRY91B0	0.53 - 0.89 IU/mL 0.63 IU/mL OK
	Low Control (Antigen) LOT RRZ91B0	0.13 - 0.29 IU/mL 0.20 IU/mL OK



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Durchgeföhrt von
Prepared by

Fikret NASUFI *Fikret Nasufi*

07. APR. 2020

Datum / Date:

Freigabe von
Approved by

Michael KAFKA *[Signature]*

08. APR. 2020

Datum / Date: