

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQRO00.02 Att.13 RQ51C00.02
---	--	-----------------------------------

TECHNOZYM ADAMTS13 ELISA 2x48T.

REF	5450501-RUO
LOT	RQ51C00.02
⌚	2027-01-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	⌚
1x	0.3 mL	HFP: QV ADAMTS-13 Conjugate	RQV52C0	2027-10-31
2x	n.a.	HFP: QS ADAMTS-13 Platte 48T.	RQS51C0	2027-03-31
2x	3 mL	HFP: QW ADAMTS-13 Activity Substrate	RQW51C0	2027-04-30
1x	6 mL	HFP: QX ADAMTS-13 Antigen Substrate	RQX51C0	2027-04-30
1x	0.7 mL	HFP: QL ADAMTS-13 Antigen Stable Peroxide	RQL51C0	2027-04-30
1x	6 mL	HFP: QK ADAMTS-13 Antigen Stop Solution	RQK51C0	2027-04-30
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 1	1RT42C2	2027-10-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 2	2RT51C0	2027-01-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 3	3RT51C0	2027-01-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 4	4RT51C0	2027-01-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 5	5RT51C0	2027-01-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen High Control	RRY51C0	2027-01-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Low Control	RRZ51C0	2027-01-31
1x	80 mL	HFP: NA wash buffer + thimerosal	RNA51C0	2027-07-31
1x	90 mL	HFP: NB Incubation buffer	RNB51C0	2027-07-31

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	ΔRFU/min Activity	≥ 200.0 RFU	371 RFU	OK	
	High Control (Activity) LOT RRY51C0	0.51 - 0.85 IU/mL	0.71 IU/mL	OK	
	Low Control (Activity) LOT RRZ51C0	0.10 - 0.24 IU/mL	0.15 IU/mL	OK	
	ΔRFU/min Antigen	≥ 200.0 RFU	534 RFU	OK	
	High Control (Antigen) LOT RRY51C0	0.59 - 0.99 IU/mL	0.83 IU/mL	OK	
	Low Control (Antigen) LOT RRZ51C0	0.08 - 0.20 IU/mL	0.17 IU/mL	OK	

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQRO00.02 Att.13 RQ51C00.02
---	---	---

Durchgeföhrt von
Prepared by

Fikret NASUFI *Fikret Nasufi*

03. DEZ. 2025

Datum / Date:

Freigabe von
Approved by

Maylis RAUSCHER *Maylis Rauscher*

03. DEZ. 2025

Datum / Date: