



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRO00.02

Att.13

RQ42C00.03

## TECHNOZYM ADAMTS13 ELISA 2x48T.

REF	5450501-RUO
LOT	RQ42C00.03
	2026-02-28

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	0.3 mL	HFP: QV ADAMTS-13 Conjugate	RQV41C0	2026-07-31
2x	n.a.	HFP: QS ADAMTS-13 Platte 48T.	RQS41C0	2026-02-28
2x	3 mL	HFP: QW ADAMTS-13 Activity Substrate	RQW41C0	2026-06-30
1x	6 mL	HFP: QL ADAMTS-13 Antigen Substrate	RQX41C0	2026-06-30
1x	0.7 mL	HFP: QL ADAMTS-13 Antigen Stable Peroxide	RQL41C0	2026-06-30
1x	6 mL	HFP: QL ADAMTS-13 Antigen Stop Solution	RQK41C0	2026-06-30
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 1	1RT42C0	2026-05-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 2	2RT42C0	2026-04-30
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 3	3RT42C0	2026-04-30
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 4	4RT42C0	2026-04-30
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 5	5RT41C0	2026-04-30
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen High Control	RRY42C0	2026-04-30
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Low Control	RRZ42C0	2026-04-30
1x	80 mL	HFP: NA wash buffer + thimerosal	RNA41C0	2026-08-31
1x	90 mL	HFP: NB Incubation buffer	RNB41C0	2026-07-31

Analytische Verfahren Analytical Procedures	Anforderung Requirement	Ergebnis Result
visuelle Kontrolle visual inspection	Content	according to packaging SOP
	Vial label	confirmed
	Box label	confirmed
	Box barcode	confirmed
	Package insert	confirmed
	Batch table	confirmed
Funktion Function	<b>ΔRFU/min Activity</b>	≥ 200.0 RFU
	<b>High Control (Activity)</b>	610 RFU
	LOT RRY42C0	0.53 - 0.88 IU/mL
	<b>Low Control (Activity)</b>	0.77 IU/mL
	LOT RRZ42C0	0.08 - 0.18 IU/mL
	<b>ΔRFU/min Antigen</b>	≥ 200.0 RFU
<b>High Control (Antigen)</b>	419 RFU	
LOT RRY42C0	0.51 - 0.85 IU/mL	
<b>Low Control (Antigen)</b>	0.74 IU/mL	
LOT RRZ42C0	0.07 - 0.17 IU/mL	
0.13 IU/mL	OK	