



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRR00.02

Att.04

RR61C00.02

TECHNOZYM ADAMTS-13 Antigen ELISA 96T.

REF	5450601-RUO
LOT	RR61C00.02
	2027-10-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	-	HFP: RS ADAMTS-13 Ag ELISA Platte 96T.	RRS61C0	2028-02-29
1x	0.3 mL	HFP: QV ADAMTS-13 Conjugate	RQV52C0	2027-10-31
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	2RT52C0	2027-10-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 3	3RT52C0	2027-10-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 4	4RT52C0	2027-10-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 5	5RT52C0	2027-10-31
1x	0.5 mL	HFP: RY ADAMTS-13 Antigen High Control	RRY52C0	2027-10-31
1x	0.5 mL	HFP: RZ ADAMTS-13 Antigen Low Control	RRZ52C0	2027-10-31
1x	80 mL	HFP: NA wash buffer + thimerosal	RNA52C0	2027-11-30
1x	90 mL	HFP: NB Incubation buffer	RNB52C0	2027-11-30
1x	12 mL	HFP: KK Stop solution for TMB	RKK61C0	2028-03-31
1x	12 mL	HFP: KN TMB Substrate	RKN53C0	2027-12-31

Analytische Verfahren Analytical Procedures	Anforderung Requirement	Ergebnis Result
visuelle Kontrolle visual inspection	Content	confirmed OK
	Vial label	confirmed OK
	Box label	confirmed OK
	Package insert	present confirmed OK
	Batch table	present confirmed OK
Verwendbarkeit Usability	deltaOD Cal1-Cal5 ≥ 0.7	1.3 OK
Kontrollwiederfindung Recovery of controls	High Control LOT RRY52C0	0.44 - 0.74 IU/mL 0.68 IU/mL OK
	Low Control LOT RRZ52C0	0.12 - 0.28 IU/mL 0.18 IU/mL OK



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRR00.02

Att.04

RR61C00.02

Durchgeföhrt von
Prepared by


Lucas HOLOVICZ

14. APR. 2026

Datum / Date:

Freigabe von
Approved by


Maylis RAUSCHER

14. APR. 2026

Datum / Date: