



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRP0.02

Att.17

RP56C0S.02

TECHNOZYM ADAMTS13 INH ELISA 48 T.

REF	5450451-RUO
LOT	RP56C0S.02
	2027-04-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	-	ADAMTS13 INH plate 48 T.	RPS55CS	2027-07-31
1x	0.3 mL	ADAMTS13 INH POX	RPV52C0	2027-07-31
1x	0.5 mL	ADAMTS13 INH Calibrator 1	1PT51C0	2027-04-30
1x	0.5 mL	ADAMTS13 INH Calibrator 2	2PT51C0	2027-04-30
1x	0.5 mL	ADAMTS13 INH Calibrator 3	3PT51C0	2027-05-31
1x	0.5 mL	ADAMTS13 INH Calibrator 4	4PT51C0	2027-05-31
1x	0.5 mL	ADAMTS13 INH Calibrator 5	5PT51C0	2027-05-31
1x	0.5 mL	ADAMTS13 INH High Control	RPY51C0	2027-05-31
1x	0.5 mL	ADAMTS13 INH Low Control	RPZ51C0	2027-05-31
1x	12 mL	Stop Solution	RKK52C0	2027-07-31
1x	12 mL	TMB Substrate	RKN52C0	2027-07-31
1x	80 mL	Wash buffer concentrate	RNA51C0	2027-07-31
1x	90 mL	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
Verwendbarkeit Usability	Kurvensteigung Slope	≥ 0.7	1.2	OK
	ADAMTS13 INH High Control LOT RPY51C0	41.89 - 69.81 U/mL	59.28 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ51C0	10.81 - 25.23 U/mL	16.99 U/mL	OK

Durchgeführt von

Prepared by

Fikret NASUFI *Fikret Nasufi*

05. SEP. 2025

Datum / Date:

Freigabe von

Approved by

Lucas
Lucas HOLOVICZ

05. SEP. 2025

Datum / Date: