



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRP0.02
Att.16
RP1CC00.02

TECHNOZYM ADAMTS13 INH ELISA 96 T.

REF 5450401-RUO
 LOT RP1CC00.02
 ⌚ 2023-01-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	⌚
1x	-	ADAMTS13 INH plate 96 T.	RPS16C0	2023-04-30
1x	0.3 mL	ADAMTS13 INH POX	RPV11C0	2023-04-30
1x	0.5 mL	ADAMTS13 INH Calibrator 1	1PT11C0	2023-05-31
1x	0.5 mL	ADAMTS13 INH Calibrator 2	2PT11C0	2023-05-31
1x	0.5 mL	ADAMTS13 INH Calibrator 3	3PT11C0	2023-05-31
1x	0.5 mL	ADAMTS13 INH Calibrator 4	4PT11C0	2023-05-31
1x	0.5 mL	ADAMTS13 INH Calibrator 5	5PT11C0	2023-05-31
1x	0.5 mL	ADAMTS13 INH High Control	RPY11C0	2023-05-31
1x	0.5 mL	ADAMTS13 INH Low Control	RPZ11C0	2023-05-31
1x	12 mL	Stop Solution	RKK11C0	2023-01-31
1x	12 mL	TMB Substrate	RKN11C0	2023-02-28
1x	80 mL	Wash buffer concentrate	RNA11C0	2023-03-31
1x	90 mL	Incubation buffer	RNB11C0	2023-03-31

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	1.5	OK
	ADAMTS13 INH High Control LOT RPY11C0	60.62 - 90.92 U/mL	83.39 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ11C0	15.33 - 35.77 U/mL	27.37 U/mL	OK

Durchgeführt von
Prepared by

Michael KAFKA

01. JUNI 2021

Datum / Date:

Freigabe von
Approved by

Fikret NASUFI

01. JUNI 2021

Datum / Date: