



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRB0.04

Att.09

RB4BC00.03

TECHNOZYM vWF:CBA Collagen Typ III ELISA Kit 96T.

REF	5450301-RUO
LOT	RB4BC00.03
	2026-07-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	⌚
1x	0.5 mL	vWF Calibrator 1	1ND32C1	2026-10-31
1x	0.5 mL	vWF Calibrator 2	2ND31C1	2026-10-31
1x	0.5 mL	vWF Calibrator 3	3ND31C1	2026-10-31
1x	0.5 mL	vWF Calibrator 4	4ND31C1	2026-10-31
1x	0.5 mL	vWF Calibrator 5	5ND31C1	2026-10-31
1x	0.5 mL	vWF High Control	AND32C1	2026-10-31
1x	0.5 mL	vWF Low Control	BND31C1	2026-10-31
1x	12 mL	TMB Substrate	RKN42C0	2026-08-31
1x	12 mL	Stop solution	RKK42C0	2026-09-30
1x	80 mL	Wash buffer concentrate	RNA41C0	2026-08-31
1x	90 mL	Incubation buffer	RNB41C0	2026-07-31
1x	-	vWF:CBA Plate Collagen Typ III	RNC45C0	2026-10-31
1x	0.3 mL	CBA Conjugate	RNE42C0	2026-10-31

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
	Package insert	present	confirmed	OK
	Batch table	present	confirmed	OK
Verwendbarkeit Usability	deltaOD Cal1-Cal5	≥ 0.7	1.5	OK
Kontrollwiederfindung Recovery of controls	vWF High Control LOT AND32C1	0.72 - 1.20 IU/mL	0.91 IU/mL	OK
	vWF Low Control LOT BND31C1	0.25 - 0.57 IU/mL	0.42 IU/mL	OK



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Durchgeföhrt von
Prepared by

Fikret NASUFI *Fikret Nasufi*

04. DEZ. 2024

Datum / Date:

Freigabe von
Approved by

Michael KAFKA *[Signature]*

04. DEZ. 2024

Datum / Date:

CERTIFICATE OF ANALYSIS

Technofluor ADAMTS13:Act



Temp.: TF0327.07

Attachment 06 DQFA00.02

FA44C00.03

REF	5800100-RUO
LOT	FA44C00.03
	2026-08-31

Content	volume	Reagent	LOT	
2x	3mL	Technofluor ADAMTS13 BUF	FAB43C0	2026-08-31
2x	1mL	Technofluor ADAMTS13 SUB	FAA43C0	2026-09-30

Analytical Procedures		Requirement	Result	
visual inspection	Content	according to packaging SOP	confirmed	OK
	Vial label	according to packaging SOP	confirmed	OK
	Vial barcode	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
Recovery of controls	Control N LOT 1P31C01	0.65 - 1.08 IU/mL	0.81 IU/mL	OK
	Control A LOT 3P42C00	0.32 - 0.54 IU/mL	0.42 IU/mL	OK

Prepared by Lucas HOLBYCZ

26. NOV. 2024
Date

Approved by Maria FAUSCHER

26. NOV. 2024
Date

CERTIFICATE OF ANALYSIS

Technofluor ADAMTS13:Act



Attachment 06 DQFA00.02

Temp.: TP0327.07

FA44C00.04

REF	5800100-RUO
LOT	FA44C00.04
	2026-08-31

Content	volume	Reagent	LOT	
2x	3mL	Technofluor ADAMTS13 BUF	FAB43C0	2026-08-31
2x	1mL	Technofluor ADAMTS13 SUB	FAA43C0	2026-09-30

Analytical Procedures	Requirement	Result		
visual inspection	Content	according to packaging SOP	confirmed	OK
	Vial label	according to packaging SOP	confirmed	OK
	Vial barcode	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
Recovery of controls	Control N LOT 1P31C01	0.65 - 1.08 IU/mL	0.81 IU/mL	OK
	Control A LOT 3P42C00	0.32 - 0.54 IU/mL	0.42 IU/mL	OK

Prepared by Smilja DURANOVIC
Duranovic

04. DEZ. 2024

Date

Approved by Michael KAFKA
[Signature]

04. DEZ. 2024

Date

CERTIFICATE OF ANALYSIS
TECHNOZYM ADAMTS13 Activity ELISA Kit



Attachment 03 DQRU00.11

Temp.: TP0327.07

RU4BC00.02

REF 5450701-RUO
LOT RU4BC00.02
 2026-04-30

Content	volume	Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	445	2026-04-30
1x	30mL	ADAMTS-13 Activity Reaction Buffer	445	2026-04-30
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	445	2026-04-30
1x	12mL	ADAMTS-13 Activity Color Reagent	445	2026-04-30
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	445	2026-04-30
1x	12mL	ADAMTS-13 Activity Stop Solution	445	2026-04-30
1x	n.a.	ADAMTS-13 Activity Plate 96T.	445	2026-04-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT42C0	2026-08-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT42C0	2026-08-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT42C0	2026-07-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT42C0	2026-08-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT42C0	2026-08-31
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY42C0	2026-08-31
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ42C0	2026-08-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT42C0	2026-08-31

Analytical Procedures		Requirement	Result	
visual inspection	Content	according to packaging SOP	confirmed	OK
	Vial label	according to packaging SOP	confirmed	OK
	Vial barcode	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	deltaOD Cal1-Cal6	≥ 0.7	1.9
Recovery of controls	ADAMTS-13 Activity High Control LOT RUY42C0	0.71 - 1.19 IU/mL	1.15 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ42C0	0.17 - 0.39 IU/mL	0.29 IU/mL	OK

Prepared by Lucas HOLYNGZ

26. NOV. 2024
Date

Approved by Fikrel NASUFI Fikrel Nasufi

26. NOV. 2024
Date