


CERTIFICATE OF ANALYSIS
TECHNOZYM ADAMTS13 Activity ELISA Kit




Attachment 03 DQRU00.11

Temp.: TF027.07

RU52C00.04

REF 5450701-US
 LOT RU52C00.04
 2026-06-30

Content	volume	Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	455	2026-06-30
1x	30mL	ADAMTS-13 Activity Reaction Buffer	455	2026-06-30
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	455	2026-06-30
1x	12mL	ADAMTS-13 Activity Color Reagent	455	2026-06-30
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	455	2026-06-30
1x	12mL	ADAMTS-13 Activity Stop Solution	455	2026-06-30
1x	n.a.	ADAMTS-13 Activity Plate 96T.	455	2026-06-30
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	2.0	OK
Recovery of controls	ADAMTS-13 Activity High Control LOT RUY42C0	0.71 - 1.19 IU/mL	0.80 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ42C0	0.17 - 0.39 IU/mL	0.24 IU/mL	OK

Prepared by Lucas HOLWIGZ

10. FEB. 2025
Date

Approved by Robert HASJFI Robert Hasch

10. FEB. 2025
Date



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRP0.02

Att.17

RP4DC0S.02

TECHNOZYM ADAMTS13 INH ELISA 48 T.

REF	5450451-RUO
LOT	RP4DC0S.02
	2026-04-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	-	ADAMTS13 INH plate 48 T.	RPS42CS	2026-04-30
1x	0.3 mL	ADAMTS13 INH POX	RPV41C0	2026-04-30
1x	0.5 mL	ADAMTS13 INH Calibrator 1	1PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Calibrator 2	2PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Calibrator 3	3PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Calibrator 4	4PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Calibrator 5	5PT41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH High Control	RPY41C0	2026-09-30
1x	0.5 mL	ADAMTS13 INH Low Control	RPZ41C0	2026-09-30
1x	12 mL	Stop Solution	RKK41C0	2026-04-30
1x	12 mL	TMB Substrate	RKN42C0	2026-08-31
1x	80 mL	Wash buffer concentrate	RNA41C0	2026-08-31
1x	90 mL	Incubation buffer	RNB41C0	2026-07-31

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 RPY41C0	41.54 - 69.24 U/mL	57.30 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ41C0	10.31 - 24.07 U/mL	16.47 U/mL	OK

Durchgeführt von
Prepared by

Lucas HOLWICZ

16. JAN. 2025


Datum / Date:

Freigabe von
Approved by


Fikret NASUFI Fikret Nasufi

16. JAN. 2025

Datum / Date:

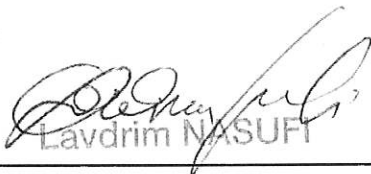
	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ2K00.02
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FVIII Inhibitorplasma HCV neg. 5x1mL

REF 5159010-RUO
LOT 2K41C0D.05
 2026-02-28

3Analytische Prozedur Analytical Procedure		Anforderung Requirement	Ergebnis Result	
pH		7.4 – 7.8	7.4	OK
Virologie Virology	HBsAg / HBsAg HIV-AK / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	Negative Negative Negative	OK
Verwendbarkeit Usability Ceveron® alpha	FVIII clotting Siron LS	19.6 – 32.6 BE/mL	28.6	OK
Etiketten und Barcode Überprüfung Label and bar code Verification			OK	

**Durchführung von
Prepared by**


Lavdrim NASUFI

110. FEB. 2025
Datum / Date:

**Freigabe von
Approved by**


Stefan BRUCKBERGER

11. FEB. 2025
Datum / Date:

CERTIFICATE OF ANALYSIS
TECHNOZYM ADAMTS13 Activity ELISA Kit



Attachment 03 DQRU00.11

Temp.: TFD327.07

RU52C00.03

REF 5450701-RUO
 LOT RU52C00.03
 2026-06-30

Content	volume	Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	455	2026-06-30
1x	30mL	ADAMTS-13 Activity Reaction Buffer	455	2026-06-30
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	455	2026-06-30
1x	12mL	ADAMTS-13 Activity Color Reagent	455	2026-06-30
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	455	2026-06-30
1x	12mL	ADAMTS-13 Activity Stop Solution	455	2026-06-30
1x	n.a.	ADAMTS-13 Activity Plate 96T.	455	2026-06-30
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	2.3
Recovery of controls	ADAMTS-13 Activity High Control LOT RUY42C0	0.71 - 1.19 IU/mL	0.79 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ42C0	0.17 - 0.39 IU/mL	0.27 IU/mL	OK

Prepared by

10. FEB. 2025
Date

Approved by

10. FEB. 2025
Date

CERTIFICATE OF ANALYSIS TECHNOLEIA D-Dimer Latex Kit



Attachment 17 DQK700.02

Temp.: TFO327.07

K943C00.02

REF	4847210-RUO
LOT	K943C00.02
⌚	2025-09-30

Content	volume	Reagent	LOT	⌚
1x	4 mL	D-Dimer Latex Reagent	K648CA0	2025-09-30
1x	7 mL	D-Dimer Reaction Buffer	K548CA0	2025-09-30
1x	8 mL	D-Dimer NaCl solution 0.9%	K441C00	2029-08-31
1x	1 mL	D-Dimer Calibrator 0 ng/mL	K331C00	2025-12-31
1x	1 mL	D-Dimer Calibrator ~ 3000 ng/mL	K141C00	2026-03-31

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
Recovery of controls	Control high LOT K241C00	1453 - 2421 ng/mL	1920 ng/mL	OK
	Control low LOT K841C00	283 - 471 ng/mL	428 ng/mL	OK

Prepared by *NIKOL NASUHI Fibret Nadeh*


12. FEB. 2025

Date


Approved by *[Signature]*


12. FEB. 2025

Date

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQRK00 01
		Att.05
		RK41C00.02

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

REF	5450311-RUO
LOT	RK41C00.02
	2025-10-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	0.5 mL	vWF Calibrator 1	1ND32C0	2025-12-31
1x	0.5 mL	vWF Calibrator 2	2ND31C0	2025-12-31
1x	0.5 mL	vWF Calibrator 3	3ND31C0	2025-12-31
1x	0.5 mL	vWF Calibrator 4	4ND31C0	2025-12-31
1x	0.5 mL	vWF Calibrator 5	5ND31C0	2025-11-30
1x	0.5 mL	vWF High Control	AND32C0	2025-11-30
1x	0.5 mL	vWF Low Control	BND31C0	2025-11-30
1x	12 mL	TMB Substrate	RKN41C0	2026-03-31
1x	12 mL	Stop solution	RKK41C0	2026-04-30
1x	80 mL	Wash buffer concentrate	RNA32C0	2025-10-31
1x	90 mL	Incubation buffer	RNB33C0	2025-12-31
1x	-	vWF:CBA Plate Collagen Typ I	RNM21C1	2026-02-28
1x	0.3 mL	CBA Conjugate	RNH22C1	2026-02-28

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 Ca11-Ca15	≥ 0.7	2.1	OK
Kontrollwiederfindung Recovery of controls	vWF High Control LOT AND32C0	0.72 - 1.20 IU/mL	1.16 IU/mL	OK
	vWF Low Control LOT BND31C0	0.25 - 0.57 IU/mL	0.42 IU/mL	OK



**ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS**

DQRK00.01

Att.05

RK41C00.02

Durchgeföhrt von
Prepared by

Fikret NASUFI *Fikret Nasufi*

24. JUNI 2024


Datum / Date:

Freigabe von
Approved by

Lucas HOLOWICZ *Lucas Holowicz*

25. JUNI 2024

Datum / Date:


	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ4D0D.02 LOT 4D31C0E.02
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Factor XIII Mangelplasma, immunads 5x1mL

REF 5194104-RUO

LOT 4D31C0E.02

 2026-04-30

Inhalt Content	Reagenz Reagent	LOT	
5 x 1mL	Factor XIII Mangelplasma, immunads	4D31C0E	2026-04-30

Analytische Verfahren Analytical Procedure	Anforderung Requirement	Ergebnis Result	
Verwendbarkeit / Usability	< 5% F XIII	0.0	OK
Etiketten und Barcode Überprüfung Label and bar code Verification		OK	

Durchführung von
Prepared by


Michael RAFIKA

12. FEB. 2025
Datum / Date:

Freigabe von
Approved by


Maria RAUSCHER

12. FEB. 2025
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