

CERTIFICATE OF ANALYSIS

AK-Calibrant



Attachment 07 DQ0U00.05

Temp.: TP0327.07

OU41C00.03

REF	5010004-RUO
LOT	OU41C00.03
	2026-07-31

Content	volume	Reagent	LOT	
1x	1 mL	AK-Calibrant Level A	1N32C01	2026-07-31
1x	1 mL	AK-Calibrant Level B	3L35C01	2026-07-31
1x	1 mL	AK-Calibrant Level C	3M32C01	2026-07-31
1x	1 mL	AK-Calibrant Level D	3N32C01	2026-07-31

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
Recovery of controls TECHNOPLASTIN HIS	Control N LOT 1P31C01	0.83 - 1.11 INR	0.96 INR	OK
	Control A LOT 3P42C00	2.02 - 2.72 INR	2.31 INR	OK

Prepared by Stefan BRUCKBERGER

28. NOV. 2024
Date

Approved by

28. NOV. 2024
Date

CERTIFICATE OF ANALYSIS
F VIII Mangelplasma, nativ 5x1 ml



Attachment 03 DQ4800.03

Temp.: TPO326.07

4841C00.02

REF	5154007-RUO
LOT	4841C00.02
⌚	2026-04-30

Analytical Procedures	Requirement	Result																								
visual inspection	Cap color	blue confirmed OK																								
	Vial type	clear glass vial 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																								
	Appearance before reconstitution	buff colored plug of lyophilized material confirmed OK																								
	Appearance after reconstitution	amber colored liquid confirmed OK																								
Virology The testing methods applied were FDA-approved or CE marked.	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab Negative Negative Positive	Negative Negative Positive OK																								
Recovery of controls FVIII	<table border="0" style="width: 100%;"> <tr> <td colspan="4">Control N</td> </tr> <tr> <td>LOT</td> <td>1P31C00</td> <td>77.3 - 128.8 %</td> <td>102.6 %</td> </tr> <tr> <td colspan="4">Control A</td> </tr> <tr> <td>LOT</td> <td>3P42C00</td> <td>25.5 - 42.5 %</td> <td>30.4 %</td> </tr> </table>	Control N				LOT	1P31C00	77.3 - 128.8 %	102.6 %	Control A				LOT	3P42C00	25.5 - 42.5 %	30.4 %	<table border="0" style="width: 100%;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;">OK</td> </tr> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 25%;">OK</td> </tr> </table>				OK				OK
Control N																										
LOT	1P31C00	77.3 - 128.8 %	102.6 %																							
Control A																										
LOT	3P42C00	25.5 - 42.5 %	30.4 %																							
			OK																							
			OK																							

Prepared by

26. NOV. 2024
Date

Approved by MAUSCHER

26. NOV. 2024
Date



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ470D.02
Att.03
4731C0D.03

F VII Mangelplasma immunads, 5x1mL

REF 5144015-RUO
LOT 4731C0D.03
 2025-08-31

Analytische Verfahren Analytical Procedures	Anforderung Requirement	Ergebnis Result
visuelle Kontrolle visual inspection	Cap color	blue
	Vial type	clear glass vial
	Vial label	according to packaging SOP
	Vial barcode	according to packaging SOP
	Box label	according to packaging SOP
	Box barcode	according to packaging SOP
	Package insert	present
	Appearance before reconstitution	buff colored plug of lyophilized material
	Appearance after reconstitution	buff colored liquid without visible particles
Virologie / Virology The testing methods applied were FDA-approved or CE marked.	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative
Kontrollwiederfindung FVII am Ceveron® Alpha	Control N LOT 1P31C00	71.3 - 118.8 % 95.3 %
Recovery of controls FVII on Ceveron® Alpha	Control A LOT 3P41C00	33.0 - 55.0 % 42.6 %

Durchgeführt von
Prepared by

26. NOV. 2024

Datum / Date:

Freigabe von
Approved by

26. NOV. 2024

Datum / Date:



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ450D.02

Att.03

4541C0D.02

F V Mangelplasma immunads, 5x1mL

REF	5134004-RUO
LOT	4541C0D.02
	2026-06-30

Analytische Verfahren Analytical Procedures	Anforderung Requirement	Ergebnis Result
visuelle Kontrolle visual inspection	Cap color	blue confirmed OK
	Vial type	clear glass vial 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
	Appearance before reconstitution	buff colored plug of lyophilized material confirmed OK
Appearance after reconstitution	buff colored liquid without visible particles confirmed OK	
Virologie / Virology The testing methods applied were FDA-approved or CE marked.	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab Negative Negative Negative	Negative Negative Negative OK
Kontrollwiederfindung FV am Ceveron® Alpha	Control N LOT 1P31C00	78.0 - 130.0 % 103.4 % OK
Recovery of controls FV on Ceveron® Alpha	Control A LOT 3P42C00	15.0 - 25.0 % 23.2 % OK

Durchgeführt von
Prepared by

LUCAS HOLLNER

26. NOV. 2024


Datum / Date:

Freigabe von
Approved by

J. RAUSCHER

26. NOV. 2024

Datum / Date:

REF 5090012-RUO
 LOT 3U41C00.02
 2026-05-31

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	red	confirmed	OK
	Vial type	clear glass vial	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
	Appearance before reconstitution	buff colored plug of lyophilized material	confirmed	OK
	Appearance after reconstitution	amber colored liquid	confirmed	OK
Virology	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	Negative Negative Negative	OK
The testing methods applied were FDA-approved or CE marked.				
Recovery of control		0.35 - 0.65 µg/mL	0.59 µg/mL	OK

Prepared by Lucas HOLMQUIST

25 NOV. 2024
Date

Approved by Stefan BRUCKBERGER

29. NOV. 2024
Date

CERTIFICATE OF ANALYSIS

Technofluor ADAMTS13:Act



Attachment 06 DQFA00.02

Temp.: TF0327.07

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 HOLEWICZ

26. NOV. 2024
Date

Approved by Maria PAUSCHER

26. NOV. 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	OK
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 HOLDINGZ

28. NOV. 2024
Date

Approved by Fikrel NASUFI Fikrel Nasufi

26. NOV. 2024
Date