

**CERTIFICATE OF ANALYSIS**  
**Factor II immunads.**



Attachment 03      DQ420D.03

Temp.: F0326.07

4231C0E.02

REF	5114008-RUO
LOT	4231C0E.02
⌚	2027-01-31

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	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 controls F II	<b>Control N</b> LOT 1P31C01	75.0 - 125.0 %	102.2 %	OK
	<b>Control A</b> LOT 3P42C00	12.8 - 21.3 %	15.1 %	OK

Prepared by Stefan BRUCKBERGER

12.7. MRZ. 2025  
Date

Approved by Smilja DURANOVIC

28. MRZ. 2025  
Date

**CERTIFICATE OF ANALYSIS**  
**Factor VII immunads**



Attachment 03      DQ470D.03

Temp.: TP0226.07

4721C0E.02

REF	5144015-RUO
LOT	4721C0E.02
⌚	2026-08-31


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	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 controls F VII	<b>Control N</b> LOT 1P31C01	71.3 - 118.8 %	103.9 %	OK
	<b>Control A</b> LOT 3P42C00	33.0 - 55.0 %	43.6 %	OK

Prepared by Stefan BROCKBERGER


28. MRZ. 2025  
Date


Approved by Smilja DURANOVIC

28. MRZ. 2025  
Date

	<b>ANALYSENZERTIFIKAT</b> <b>CERTIFICATE OF ANALYSIS</b>	DQRP0.02 Att.17 RP4BC0S.01
---	---	----------------------------------

## TECHNOZYM ADAMTS13 INH ELISA 48 T.

REF	5450451-RUO
LOT	RP4BC0S.01
	2026-04-30

Inhalt Content	Volumen volume	Reagenz Reagent	<span style="border: 1px solid black; padding: 2px;">LOT</span>	
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	<b>Kurvensteigung Slope</b>	≥ 0.7	1.2	OK
	<b>ADAMTS13 INH High Control</b> LOT RPY41C0	41.54 - 69.24 U/mL	57.89 U/mL	OK
	<b>ADAMTS13 INH Low Control</b> LOT RPZ41C0	10.31 - 24.07 U/mL	17.14 U/mL	OK

Durchgeführt von  
Prepared by

  
Lucas HOLOWICZ

09. OKT. 2024

Datum / Date:

Freigabe von  
Approved by

  
Maylis RAUSCHER

09. OKT. 2024

Datum / Date:

**CERTIFICATE OF ANALYSIS**  
**Technofluor ADAMTS13:Act 0 Cal**



Attachment 07 DQFA00.02

Temp.: TP0336.07

FAC42C0.03

REF 5800102-RUO  
 LOT FAC42C0.03  
 ⌚ 2026-09-30

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	grey	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	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab  The testing methods applied were FDA-approved or CE marked.	Negative Negative Negative	Negative Negative Negative	OK
Recovery of controls	<b>Control N</b> LOT 1P31C01	0.65 - 1.08 IU/mL	0.89 IU/mL	OK
	<b>Control A</b> LOT 3P42C00	0.32 - 0.54 IU/mL	0.43 IU/mL	OK

Prepared by Stefan BRUCKBERGER

27. MRZ. 2025  
Date

Approved by Smilja DURANOVIC

28. MRZ. 2025  
Date