

CERTIFICATE OF ANALYSIS TECHNOCHROM C1-INH



Attachment 16 DQ0J00.03

0J54C00.02

Temp.: TQ0327.07

REF 5345003-RUO
LOT 0J54C00.02
⌚ 2026-07-31

Content	volume	Reagent	LOT	⌚
1x	1mL	Coagulation Control N f. C1-INH	1P51CC1H	2027-03-31
1x	1mL	Coagulation Control A f. C1-INH	3P52CC1H	2027-03-31
1x	see label	Coagulation Reference f. C1-INH	1R53CC1H	2027-03-31
1x	3mL	Substrate C1-1	8C52C00	2027-03-31
1x	3mL	C1-Esterase	7B42C00	2026-07-31
1x	25mL	Sample Buffer A	9M51C00	2030-03-31
1x	20mL	Reaction Buffer B	9N51C00	2030-03-31

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 N LOT 1P51CC1H	88.4 - 147.4 %	109.6 %	OK
	Control A LOT 3P52CC1H	39.7 - 66.1 %	49.6 %	OK

Prepared by

Lavdrim NASUFI

11. JUNI 2025

Date

Approved by

Maylis RAUSCHER

11. JUNI 2025

Date

CERTIFICATE OF ANALYSIS
HFP: GA PUK mAb 0.5 mg



Temp.: TPO325 07

RGA6104

REF TH1000GA
LOT RGA6104

2025-05-20
 2028-03-31

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	white	confirmed	OK
	Vial type	clear glass vial	confirmed	OK
	Appearance before reconstitution	white colored plug of lyophilized material	confirmed	OK
	Appearance after reconstitution	clear liquid	confirmed	OK
Function		positive affinity to scuPA	positive	OK
		negative affinity to uPA	negative	OK

Prepared by

20. MAI 2025

Date

Approved by

20. MAI 2025

Date