CERTIFICATE OF ANALYSIS TECHNOCHROM C1-INH



Attachment 16

DQ0J00.03

0J55C00.02

REF

5345003-RUO

0J55C00.02

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2027-02-28

Content	volume 1mL	Reagent	LOT	8		
1x		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	8C51C00	2027-02-28		
1x	3mL	C1-Esterase	7B51C00	2027-07-31		
1x	25mL	Sample Buffer A	9M51C00	2030-03-31		
1x	20mL	Reaction Buffer B	9N51C00	2030-03-31		

Analytical Procedures			Requirement				Result		
	Content	accordi	according to packaging SOP			confirmed		ок	
	Vial label	accordi	according to packaging SOP				confirmed		
visual inspection	Vial barcode	accordi	according to packaging SOP				confirmed		
	Box label	accordi	according to packaging SOP				confirmed		
	Box barcode	accordi	according to packaging SOP				confirmed		
	Package insert		present			confirmed		ок	
	Control N	88.4	-	147.4	%	119.8	%	ок	
Description of controls	LOT 1P51CC1H	00.4							
Recovery of controls	Control A	39.7	-	66.1	%	51.2	%	ок	
	LOT 3P52CC1H	39.7							

Prepared by

AAAAMISCHER

2 0. AUG. 2025

Date

Approved by

2 n. AUG. 2025

Date