

CERTIFICATE OF ANALYSIS

Fletcher Trait Plasma



Attachment 03 DQ4P00.03

Temp.: TFO336.07

4P41C01.03

REF 5205006-RUO
LOT 4P41C01.03
⌚ 2027-09-30

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		HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	OK
The testing methods applied were FDA-approved or CE marked.				
Recovery of controls Prekalikrein	Control N			
	LOT	1P42C00	81.8 - 136.3 %	115.0 % OK
	Control A			
	LOT	3P51C00	48.0 - 80.0 %	71.5 % OK

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25. NOV. 2025

Date

Approved by

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26. NOV. 2025

Date