


CERTIFICATE OF ANALYSIS
Fletcher Trait Plasma



Temp.: TFD26.07

Attachment 03 DQ4P00.03

4P51C00.01

REF 5205006-RUO
LOT 4P51C00.01
 2027-10-31

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 Prekalikrein	Control N LOT 1P53C00	81.8 - 136.3 %	117.4 %	OK
	Control A LOT 3P54C00	48.0 - 80.0 %	76.0 %	OK

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05. MRZ. 2026
 Date

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05. MRZ. 2026
 Date