

# CERTIFICATE OF ANALYSIS

## Fitzgerald Trait Plasma



Attachment 03 DQ4K00.04

4K51C0D.02

Temp.: TFO246.07

REF 5204006-RUO  
LOT 4K51C0D.02  
2027-03-31

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	OK
The testing methods applied were FDA-approved or CE marked.				
Recovery of controls	Control N			
	LOT 1P31C01	88.5 - 147.5 %	110.0 %	OK
	Control A			
	LOT 3P42C00	36.0 - 60.0 %	47.3 %	OK

Prepared by

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25. APR. 2025

Date

Approved by

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28. APR. 2025

Date