

# CERTIFICATE OF ANALYSIS

## Fitzgerald Trait Plasma



Attachment 03 DQ4K00.04

Temp.: T0326.07

4K51C0D.04

REF 5204006-RUO  
 LOT 4K51C0D.04  
 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 The testing methods applied were FDA-approved or CE marked.		Negative Negative Negative	Negative Negative Negative	OK
Recovery of controls	<b>Control N</b> LOT 1P42C00	84.8 - 141.3 %	108.7 %	OK
	<b>Control A</b> LOT 3P51C00	41.3 - 68.8 %	54.0 %	OK

Prepared by

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12. SEP. 2025

Date

Approved by

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15. SEP. 2025

Date