



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4K00.03  
Att.03  
  
4K41C0D.03

## Fitzgerald Trait Plasma 2x1 ml

REF	5204006-RUO
LOT	4K41C0D.03
	2026-05-31

Analytische Verfahren Analytical Procedures	Anforderung Requirement	Ergebnis Result
visuelle Kontrolle 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	buff colored liquid confirmed OK
Virologie / Virology  The testing methods applied were FDA-approved or CE marked.	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab  Negative Negative Negative	Negative Negative Negative  OK
Kontrollwiederfindung HMWK am Ceveron® alpha	Control N LOT 1P31C01	88.5 - 147.5 % 105.4 % OK
Recovery of controls HMWK on Ceveron® alpha	Control A LOT 3P42C00	36.0 - 60.0 % 46.7 % OK

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