



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4K00.03

Att.03

4K04C0D.03

Fitzgerald Trait Plasma 2x1 ml

REF	5204006
LOT	4K04C0D.03
	2022-05-31

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 Recovery of controls HMWK on Ceveron® alpha	<table style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">Control N</td> </tr> <tr> <td>LOT 1P02C00</td> <td>60.0 - 100.0 %</td> </tr> <tr> <td colspan="2">Control A</td> </tr> <tr> <td>LOT 3P71B01</td> <td>23.1 - 38.5 %</td> </tr> </table>	Control N		LOT 1P02C00	60.0 - 100.0 %	Control A		LOT 3P71B01	23.1 - 38.5 %	<table style="width: 100%; border-collapse: collapse;"> <tr> <td>81.3 %</td> <td>OK</td> </tr> <tr> <td>32.4 %</td> <td>OK</td> </tr> </table>	81.3 %	OK	32.4 %	OK
Control N														
LOT 1P02C00	60.0 - 100.0 %													
Control A														
LOT 3P71B01	23.1 - 38.5 %													
81.3 %	OK													
32.4 %	OK													

Durchgeführt von
Prepared by

Lavdrim NASUFI

24. JUNI 2020

Datum / Date:

Freigabe von
Approved by

Eva Maria HAGER

24. JUNI 2020

Datum / Date: