



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4E00.04

Att.03

4E01C00.01

F XI Mangelplasma nativ, 5x1mL

REF	5184004
LOT	4E01C00.01
	2022-02-28

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 without visible particles 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 Positive	Negative Negative Positive OK
Kontrollwiederfindung F XI am Ceveron® Alpha	Control N LOT 1P02C00	72.0 - 120.0 % 103.3 % OK
Recovery of controls F XI on Ceveron® Alpha	Control A LOT 3P91B00	30.8 - 51.3 % 39.9 % OK

Durchgeführt von
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20. AUG. 2020

Datum / Date:

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