



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4E00.04

Att.03

4E92B00.01

F XI Mangelplasma nativ, 5x1mL

REF 5184004
LOT 4E92B00.01
2021-08-31

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 without visible particles	confirmed	OK	
Virologie / Virology	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab The testing methods applied were FDA-approved or CE marked.	Negative Negative Positive	Negative Negative Positive	OK
Kontrollwiederfindung F XI am Ceveron® Alpha	Control N LOT 1P71B01	83.4 - 139.1 %	98.8 %	OK
Recovery of controls F XI on Ceveron® Alpha	Control A LOT 3P71B01	32.8 - 54.6 %	38.7 %	OK

Durchgeführt von

Prepared by

Suzana GRESAK PODAKAR
Suzana Gresak Podakar

13. NOV. 2019

Datum / Date:

Freigabe von

Approved by

Stefan STEINER
Stefan Steiner

14. NOV. 2019

Datum / Date: