



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4Z00.02

Att.03

4Z72B00.01

F XII Mangelplasma nativ, 5x1mL

REF

5194008

LOT

4Z72B00.01



2019-10-31

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	Negative Negative Negative	Negative Negative Negative	OK
The testing methods applied were FDA-approved or CE marked.				
Kontrollwiederfindung F XII am Ceveron® Alpha	Control N LOT 1P71B00	89.3 - 148.9 %	112.1 %	OK
Recovery of controls F XII on Ceveron® Alpha	Control A LOT 3P71B00	43.1 - 71.8 %	49.3 %	OK

Durchgeführt von
Prepared by

Suzana GRESAK PODAKAR

26. APR. 2018

Datum / Date:

Freigabe von
Approved by

Eva Maria HAGER

26. APR. 2018

Datum / Date: