



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ490D.03

Att.03

4982B0D.01

F IX Mangelplasma immunads, 5x1mL

REF	5164003
LOT	4982B0D.01
	2020-03-31

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 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 FIX am Ceveron® Alpha	Control N LOT 1P71B00	95.2 - 158.7 % 109.6 % OK
Recovery of controls FIX on Ceveron® Alpha	Control A LOT 3P71B00	17.0 - 28.3 % 21.0 % OK

Durchgeführt von
Prepared by

Eva Maria HAGER
Eva Maria Hager

24. APR. 2018

Datum / Date:

Freigabe von
Approved by

Suzana GRESAK PODAKAR
Suzana Gresak Podakar

24. APR. 2018

Datum / Date: