



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4900.02

Att.04

4984B00.01

F IX Mangelplasma nativ, 50x1mL

REF	5164016
LOT	4984B00.01
	2020-07-31

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 FIX am Ceveron® Alpha	Control N LOT 1P71B01	95.2 - 158.7 %	103.4 %	OK
Recovery of controls FIX on Ceveron® Alpha	Control A LOT 3P71B01	17.0 - 28.3 %	19.8 %	OK

Durchgeführt von
Prepared by

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23. AUG. 2018

Datum / Date:

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23. AUG. 2018

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