



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4Z00.02

Att.03

4Z72B00.02

F XII Mangelplasma nativ, 5x1mL

REF	5194008
LOT	4Z72B00.02
⌚	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 1P71B01	89.3 - 148.9 %	119.8 % OK
Recovery of controls F XII on Ceveron® Alpha	Control A LOT 3P71B01	43.1 - 71.8 %	56.8 % OK

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