

	<b>ANALYSENZERTIFIKAT</b> <b>CERTIFICATE OF ANALYSIS</b>	DQ4Z00.02 Att.03 4Z72B01.01
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## F XII Mangelplasma nativ, 5x1mL

REF	5194008
LOT	4Z72B01.01
⌚	2021-06-30

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	<b>Control N</b> LOT 1P02C00	82.5 - 137.5 %	96.1 %	OK
Recovery of controls F XII on Ceveron® Alpha	<b>Control A</b> LOT 3P91B00	33.8 - 56.3 %	44.3 %	OK

Durchgeführt von

Prepared by

  
**Lavdrim NASUFI**

15. JUNI 2020

Datum / Date:

Freigabe von

Approved by

  
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15. JUNI 2020

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