



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4Z00.02

Att.03

4Z31C00.02

F XII Mangelplasma nativ, 5x1mL

REF	5194008-RUO
LOT	4Z31C00.02
⌚	2025-07-31

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	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 1P31C00	86.3 - 143.8 %	103.9 %	OK
Recovery of controls F XII on Ceveron® Alpha	Control A LOT 3P42C00	30.0 - 50.0 %	45.4 %	OK

Durchgeführt von

Prepared by

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02. OKT. 2024

Datum / Date:

Freigabe von

Approved by

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02. OKT. 2024

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