



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4000.02

Att.03

4011C01.02

F X Mangelplasma nativ, 5x1mL

REF	5174004-RUO
LOT	4011C01.02
	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 The testing methods applied were FDA-approved or CE marked.	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Positive	Negative Negative Positive OK
Kontrollwiederfindung F X am Ceveron® Alpha	Control N LOT 1P11C01	80.3 - 133.8 %	105.0 % OK
Recovery of controls F X on Ceveron® Alpha	Control A LOT 3P23C00	14.3 - 23.8 %	19.6 % OK

Durchgeführt von
Prepared by

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10. OKT. 2024

Datum / Date:

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Approved by

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10. OKT. 2024

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