



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ0N00.04

Att.22

0N11C00.03

TECHNOCHROM FVIII:C 40 T.

REF 5344101-RUO

LOT 0N11C00.03

2023-02-28

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	1 mL	Ref. Standard 1	2W91B01	2023-02-28
1x	1 mL	Ref. Standard 2	2X91B01	2023-02-28
1x	1 mL	Ref. Standard 3	2Y91B01	2023-02-28
1x	1 mL	Ref. Standard 4	2Z91B01	2023-02-28
2x	2 mL	Reagent A	7M91B01	2023-02-28
2x	2 mL	Reagent B	7L91B01	2023-02-28
3x	30 mL	FVIII Verdünnungspuffer	9Y91B00	2024-02-29
2x	8 mL	FVIII Reaktionspuffer	9T92B00	2024-06-30
2x	2 mL	Substrate FXa	8M01C00	2024-04-30

Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result	
visuelle Kontrolle visual inspection	Content	according to packaging SOP	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
Kontrollwiederfindung Recovery of controls	Control N LOT 1P02C01	57.0 - 95.0 %	79.7 %	OK
	Control A LOT 3P91B01	18.8 - 31.3 %	19.0 %	OK

Durchgeführt von
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05. MAI 2021

Datum / Date:

Freigabe von
Approved by
Lucas HOLOWICZ

05. MAI 2021

Datum / Date: