



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ0N00.03

Att.22

0N02C00.01

## TECHNOCHROM FVIII:C 40 T.

REF 5344101  
LOT 0N02C00.01  
🕒 2021-07-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	🕒
1x	1 mL	Ref. Standard 1	2W91B00	2021-10-31
1x	1 mL	Ref. Standard 2	2X91B00	2021-10-31
1x	1 mL	Ref. Standard 3	2Y91B00	2021-10-31
1x	1 mL	Ref. Standard 4	2Z91B00	2021-10-31
2x	2 mL	Reagent A	7M91B00	2021-07-31
2x	2 mL	Reagent B	7L91B00	2021-07-31
3x	30 mL	FVIII Verdünnungspuffer	9Y91B00	2024-02-29
2x	8 mL	FVIII Reaktionspuffer	9T92B00	2024-06-30
2x	2 mL	Substrate Fxa 10 µmol	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	<b>Control N</b> LOT 1P02C00	57.0 - 95.0 %	76.7 %	OK
	<b>Control A</b> LOT 3P91B00	18.8 - 31.3 %	21.5 %	OK

Durchgeführt von  
Prepared by

Lavdrim NASUFI

29. SEP. 2020

Datum / Date:

Freigabe von  
Approved by

Christoph ENNE

30. SEP. 2020

Datum / Date: