

CERTIFICATE OF ANALYSIS

AK-Calibrant



Attachment 07 DQ0U00.05

Temp.: TFC027.07

0U51C00.03

REF	5010004-RUO
LOT	0U51C00.03
	2026-11-30

Content	volume	Reagent	LOT	
1x	1 mL	AK-Calibrant Level A	1N42C00	2026-11-30
1x	1 mL	AK-Calibrant Level B	3L46C00	2026-11-30
1x	1 mL	AK-Calibrant Level C	3M45C00	2026-11-30
1x	1 mL	AK-Calibrant Level D	3N46C00	2026-12-31

Analytical Procedures		Requirement	Result	
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
	Batch table	present	confirmed	OK
Recovery of controls TECHNOPLASTIN HIS	Control N LOT 1P31C01	0.83 - 1.11 INR	0.96 INR	OK
	Control A LOT 3P42C00	2.02 - 2.72 INR	2.46 INR	OK

Prepared by Stefan BRUCKBERGER

26. MRZ. 2025
Date

Approved by Michael KAFKA

26. MRZ. 2025
Date