

CERTIFICATE OF ANALYSIS
AK-Calibrant



Temp.: TF0327.07

Attachment 07 DQ0U00.05
0U51C00.02

REF 5010004-RUO
LOT 0U51C00.02
⌚ 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	0.92	INR	OK
	Control A LOT 3P42C00		2.02	-	2.72	INR	2.34	INR	OK

Prepared by  Lavdrim NASUFI

10. MRZ. 2025
Date

Approved by  Stefan BRUCKBERGER

11. MRZ. 2025
Date