

CERTIFICATE OF ANALYSIS

AK-Calibrant



Attachment 07 DQ0U00.05

Temp.: TP0327.07

0U32C00.04

REF	5010004-RUO
LOT	0U32C00.04
	2025-09-30

Content	volume	Reagent	LOT	
1x	1 mL	AK-Calibrant Level A	1N32C00	2025-09-30
1x	1 mL	AK-Calibrant Level B	3L35C00	2025-09-30
1x	1 mL	AK-Calibrant Level C	3M32C00	2025-09-30
1x	1 mL	AK-Calibrant Level D	3N32C00	2025-09-30

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 1P31C00	0.83 - 1.11 INR	0.95 INR	OK
	Control A LOT 3P42C00	2.02 - 2.72 INR	2.37 INR	OK

Prepared by Smilja DURANOVIC
Duranovic

12. JUNI 2024
Date

Approved by Michael KAFKA
[Signature]

12. JUNI 2024
Date