

CERTIFICATE OF ANALYSIS  
AK-Calibrant



Attachment 07      DQ0U00.06

Temp.: TFC0327.07

0U54C00.01

REF      5010004-RUO  
LOT      0U54C00.01  
⌚      2027-07-31

Content	volume	Reagent	LOT	⌚
1x	1 mL	AK-Calibrant Level A	1N42C01	2027-07-31
1x	1 mL	AK-Calibrant Level B	3L46C01	2027-07-31
1x	1 mL	AK-Calibrant Level C	3M45C01	2027-07-31
1x	1 mL	AK-Calibrant Level D	3N46C01	2027-07-31

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	<b>Control N</b>								
	LOT	1P42C00	0.79	-	1.07	INR	0.97	INR	OK
	<b>Control A</b>								
	LOT	3P42C01	2.02	-	2.72	INR	2.38	INR	OK

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21. AUG. 2025  
Date

Approved by        
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21. AUG. 2025  
Date