

# CERTIFICATE OF ANALYSIS

## AK-Calibrant



Temp.: TP0327.07

Attachment 07      DQ0U00.05

OU51C00.02

|     |             |
|-----|-------------|
| REF | 5010004-RUO |
| LOT | OU51C00.02  |
|     | 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<br>TECHNOPLASTIN HIS | <b>Control N</b><br>LOT 1P31C01 | 0.83 - 1.11 INR            | 0.92 INR  | OK |
|   | <b>Control A</b><br>LOT 3P42C00 | 2.02 - 2.72 INR            | 2.34 INR  | OK |

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10. MRZ. 2025  
Date

Approved by  Stefan BRUCKBERGER

11. MRZ. 2025  
Date