

|                                                |                                                                  |                                                             |
|------------------------------------------------|------------------------------------------------------------------|-------------------------------------------------------------|
| <div><div>technoclone</div><div>TC</div></div> | <div>ANALYSENZERTIFIKAT</div> <div>CERTIFICATE OF ANALYSIS</div> | <div>DQRP0.02</div> <div>Att.18</div> <div>6PT42C0.02</div> |
|------------------------------------------------|------------------------------------------------------------------|-------------------------------------------------------------|

TECHNOZYM ADAMTS13 INH Calibrator Set 5x0.5 mL

REF

LOT

5450461-RUO

6PT42C0.02

2026-09-30

| Inhalt<br>Content | Volumen<br>volume | Reagenz<br>Reagent        | LOT     |            |
|-------------------|-------------------|---------------------------|---------|------------|
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 1 | 1PT41C0 | 2026-09-30 |
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 2 | 2PT41C0 | 2026-09-30 |
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 3 | 3PT41C0 | 2026-09-30 |
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 4 | 4PT41C0 | 2026-09-30 |
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 5 | 5PT41C0 | 2026-09-30 |

| Analytische Verfahren<br>Analytical Procedures |                                          | Anforderung<br>Requirement | Ergebnis<br>Result |    |
|------------------------------------------------|------------------------------------------|----------------------------|--------------------|----|
| visuelle Kontrolle<br>visual inspection        | Content                                  | according to packaging SOP | confirmed          | OK |
|                                                | Vial label                               | 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 |
|                                                |                                          |                            |                    |    |
| Verwendung<br>Usability                        | Kurvensteigung<br>Slope                  | ≥ 0.7                      | 0.9                | OK |
|                                                | ADAMTS13 INH High Control<br>LOT RPY41C0 | 41.54 - 69.24 U/mL         | 62.55 U/mL         | OK |
|                                                | ADAMTS13 INH Low Control<br>LOT RPZ41C0  | 10.31 - 24.07 U/mL         | 16.35 U/mL         | OK |

Durchgeführt von  
Prepared by

Lucas HOLOWICZ

Freigabe von  
Approved by

Maylis RAUSCHER

09. OKT. 2024

Datum / Date:

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