

|                                                                                   |                                                              |            |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------|------------|
|  | <h1>ANALYSENZERTIFIKAT</h1> <h2>CERTIFICATE OF ANALYSIS</h2> | DQRP0.02   |
|                                                                                   |                                                              | Att.18     |
|                                                                                   |                                                              | 6PT51C0.02 |

# TECHNOZYM ADAMTS13 INH Calibrator Set 5x0.5 mL

|                                                                                   |             |
|-----------------------------------------------------------------------------------|-------------|
| REF                                                                               | 5450461-RUO |
| LOT                                                                               | 6PT51C0.02  |
|  | 2027-04-30  |

| Inhalt<br>Content | Volumen<br>volume | Reagenz<br>Reagent        | LOT     |  |
|-------------------|-------------------|---------------------------|---------|-------------------------------------------------------------------------------------|
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 1 | 1PT51C0 | 2027-04-30                                                                          |
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 2 | 2PT51C0 | 2027-04-30                                                                          |
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 3 | 3PT51C0 | 2027-05-31                                                                          |
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 4 | 4PT51C0 | 2027-05-31                                                                          |
| 1x                | 0.5 mL            | ADAMTS13 INH Calibrator 5 | 5PT51C0 | 2027-05-31                                                                          |

| 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                      | 1.2                | OK |
|                                                | ADAMTS13 INH High Control<br>LOT RPY51C0 | 41.89 - 69.81 U/mL         | 62.59 U/mL         | OK |
|                                                | ADAMTS13 INH Low Control<br>LOT RPZ51C0  | 10.81 - 25.23 U/mL         | 17.51 U/mL         | OK |

Durchgeföhrt von  
Prepared by

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04. SEP. 2025

Datum / Date:

Freigabe von  
Approved by

Lucas HOLOVICZ *Lucas HoloVICZ*

05. SEP. 2025

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