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|---|---|------------|
|  | <b>ANALYSENZERTIFIKAT</b><br><b>CERTIFICATE OF ANALYSIS</b> | DQRU00.04  |
|   |   | Att.05     |
|   |   | RU89B00.02 |

## TECHNOZYM® ADAMTS-13 Activity ELISA 96T.

|   |            |
|---|------------|
| REF   | 5450701    |
| LOT   | RU89B00.02 |
|  | 2020-03-31 |

| Inhalt<br>Content | Volumen<br>volume | Reagenz<br>Reagent                     | LOT     |  |
|-------------------|-------------------|--|---------|---|
| 2x                | 6mL               | ADAMTS-13 Activity vWF73 Substrate     | 840     | 2020-03-31  |
| 1x                | 30mL              | ADAMTS-13 Activity Reaction Buffer     | 840     | 2020-03-31  |
| 1x                | 12mL              | ADAMTS-13 Activity HRP Conj Antibody   | 840     | 2020-03-31  |
| 1x                | 12mL              | ADAMTS-13 Activity Color Reagent       | 840     | 2020-03-31  |
| 1x                | 53mL              | ADAMTS-13 Activity Wash Buffer Conc    | 840     | 2020-03-31  |
| 1x                | 12mL              | ADAMTS-13 Activity Stop Solution       | 840     | 2020-03-31  |
| 1x                | n.a.              | ADAMTS-13 Activity Plate 96T.          | 840     | 2020-03-31  |
| 1x                | n.a.              | ADAMTS-13 Activity sample dilution MTP | 840     | 2020-03-31  |
| 3x                | n.a.              | ADAMTS-13 Activity Plate Seal          | 840     | 2020-03-31  |
| 1x                | 0.5mL             | UT ADAMTS-13 Activity Calibrator 1     | 1UT81B0 | 2020-06-30  |
| 1x                | 0.5mL             | UT ADAMTS-13 Activity Calibrator 2     | 2UT81B0 | 2020-06-30  |
| 1x                | 0.5mL             | UT ADAMTS-13 Activity Calibrator 3     | 3UT82B0 | 2020-06-30  |
| 1x                | 0.5mL             | UT ADAMTS-13 Activity Calibrator 4     | 4UT81B0 | 2020-06-30  |
| 1x                | 0.5mL             | UT ADAMTS-13 Activity Calibrator 6     | 6UT81B0 | 2020-06-30  |
| 1x                | 0.5mL             | UY ADAMTS-13 Activity High Control     | RUY81B0 | 2020-06-30  |
| 1x                | 0.5mL             | UZ ADAMTS-13 Activity Low Control      | RUZ81B0 | 2020-06-30  |
| 1x                | 0.5mL             | UT ADAMTS-13 Activity Calibrator 5     | 5UT81B0 | 2020-06-30  |

| 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     |
|  | 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                        |
| Verwendbarkeit<br>Usability                    | deltaOD Cal1-Cal6    ≥    0.7                  | 1.4    OK   |
| Kontrollwiederfindung<br>Recovery of controls  | ADAMTS-13 Activity High Control<br>LOT RUY81B0 | 0.53    -    0.89    IU/mL    0.79    IU/mL    OK |
|  | ADAMTS-13 Activity Low Control<br>LOT RUZ81B0  | 0.13    -    0.29    IU/mL    0.28    IU/mL    OK |



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Durchgeföhrt von  
Prepared by

Mikrot NASUFI *Fikret Nasech*

22. OKT. 2018

Datum / Date:

Freigabe von  
Approved by

Michael KAFKA *[Signature]*

22. OKT. 2018

Datum / Date: