



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRU00.06

Att.08

RU0VC00.01

TECHNOZYM® ADAMTS-13 Activity ELISA 96T.

| | |
|-----|-------------|
| REF | 5450701-RUO |
| LOT | RU0VC00.01 |
| | 2022-04-30 |

| Inhalt Content | Volumen volume | Reagenz Reagent | LOT | |
|-------------------|-------------------|--------------------------------------|---------|------------|
| 2x | 6mL | ADAMTS-13 Activity vWF73 Substrate | 050 | 2022-05-31 |
| 1x | 30mL | ADAMTS-13 Activity Reaction Buffer | 050 | 2022-05-31 |
| 1x | 12mL | ADAMTS-13 Activity HRP Conj Antibody | 050 | 2022-05-31 |
| 1x | 12mL | ADAMTS-13 Activity Color Reagent | 050 | 2022-05-31 |
| 1x | 53mL | ADAMTS-13 Activity Wash Buffer Conc | 050 | 2022-05-31 |
| 1x | 12mL | ADAMTS-13 Activity Stop Solution | 050 | 2022-05-31 |
| 1x | n.a. | ADAMTS-13 Activity Plate 96T. | 050 | 2022-05-31 |
| 1x | 0.5mL | UT ADAMTS-13 Activity Calibrator 1 | 1UT01C0 | 2022-04-30 |
| 1x | 0.5mL | UT ADAMTS-13 Activity Calibrator 2 | 2UT01C0 | 2022-04-30 |
| 1x | 0.5mL | UT ADAMTS-13 Activity Calibrator 3 | 3UT01C0 | 2022-04-30 |
| 1x | 0.5mL | UT ADAMTS-13 Activity Calibrator 4 | 4UT01C0 | 2022-04-30 |
| 1x | 0.5mL | UT ADAMTS-13 Activity Calibrator 6 | 6UT01C0 | 2022-04-30 |
| 1x | 0.5mL | UY ADAMTS-13 Activity High Control | RUY01C0 | 2022-04-30 |
| 1x | 0.5mL | UZ ADAMTS-13 Activity Low Control | RUZ01C0 | 2022-04-30 |
| 1x | 0.5mL | UT ADAMTS-13 Activity Calibrator 5 | 5UT01C0 | 2022-04-30 |

| Analytische Verfahren Analytical Procedures | Anforderung Requirement | Ergebnis Result |
|--|--|------------------------------------|
| visuelle Kontrolle visual inspection | Content | confirmed OK |
| | Vial label | confirmed OK |
| | Vial barcode | confirmed OK |
| | Box label | confirmed OK |
| | Box barcode | confirmed OK |
| | Package insert | present confirmed OK |
| | Batch table | present confirmed OK |
| | Verwendbarkeit Usability | deltaOD Cal1-Cal6 ≥ 0.7 |
| Kontrollwiederfindung Recovery of controls | ADAMTS-13 Activity High Control LOT RUY01C0 | 0.52 - 0.86 IU/mL 0.75 IU/mL OK |
| | ADAMTS-13 Activity Low Control LOT RUZ01C0 | 0.13 - 0.29 IU/mL 0.21 IU/mL OK |



**ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS**

DQRU00.06

Att.08

RU0VC00.01

Durchgeföhrt von

Prepared by

Fikret NASUFI *Fikret Nasch*

22. DEZ. 2020

Datum / Date:

Freigabe von

Approved by

Alessandro BENIGNI

22-Dez-2020

Datum / Date: