



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQRK00.01

Att.05

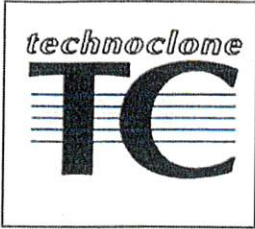
RK12C00.02

## TECHNOZYM vWF:CBA Collagen Typ I ELISA Kit 96T.

|     |             |
|-----|-------------|
| REF | 5450311-RUO |
| LOT | RK12C00.02  |
|     | 2022-09-30  |

| Inhalt<br>Content | Volumen<br>volume | Reagenz<br>Reagent           | LOT     |            |
|-------------------|-------------------|------------------------------|---------|------------|
| 1x                | 0.5 mL            | vWF Calibrator 1             | 1ND02C0 | 2022-09-30 |
| 1x                | 0.5 mL            | vWF Calibrator 2             | 2ND02C0 | 2022-09-30 |
| 1x                | 0.5 mL            | vWF Calibrator 3             | 3ND02C0 | 2022-10-31 |
| 1x                | 0.5 mL            | vWF Calibrator 4             | 4ND02C0 | 2022-10-31 |
| 1x                | 0.5 mL            | vWF Calibrator 5             | 5ND02C0 | 2022-09-30 |
| 1x                | 0.5 mL            | vWF High Control             | AND02C0 | 2022-10-31 |
| 1x                | 0.5 mL            | vWF Low Control              | BND02C0 | 2022-10-31 |
| 1x                | 12 mL             | TMB Substrate                | RKN11C0 | 2023-02-28 |
| 1x                | 12 mL             | Stop solution                | RKK11C0 | 2023-01-31 |
| 1x                | 80 mL             | Wash buffer concentrate      | RNA11C0 | 2023-03-31 |
| 1x                | 90 mL             | Incubation buffer            | RNB11C0 | 2023-03-31 |
| 1x                | -                 | vWF:CBA Plate Collagen Typ I | RNM11C0 | 2023-05-31 |
| 1x                | 0.3 mL            | CBA Conjugate                | RNH01C0 | 2022-09-30 |

| Analytische Verfahren<br>Analytical Procedures | Anforderung<br>Requirement             | Ergebnis<br>Result         |
|--|--|----------------------------|
| visuelle Kontrolle<br>visual inspection        | Content                                | according to packaging SOP |
|  | Vial label                             | according to packaging SOP |
|  | Box label                              | according to packaging SOP |
|  | Package insert                         | present                    |
|  | Batch table                            | present                    |
| Verwendbarkeit<br>Usability                    | <b>deltaOD Ca11-Ca15</b>               | ≥ 0.7                      |
| Kontrollwiederfindung<br>Recovery of controls  | <b>vWF High Control</b><br>LOT AND02C0 | 0.80 - 1.34 IU/mL          |
|  | <b>vWF Low Control</b><br>LOT BND02C0  | 0.19 - 0.45 IU/mL          |



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Durchgeföhrt von  
Prepared by

Michael KAFKA 

15. JUNI 2021  
Datum / Date:

Freigabe von  
Approved by

Fikret NASUFI 

15. JUNI 2021  
Datum / Date: