



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ490D.03

Att.03

4931C0D.03

## F IX Mangelplasma immunads, 5x1mL

|     |             |
|-----|-------------|
| REF | 5164003-RUO |
| LOT | 4931C0D.03  |
|     | 2025-03-31  |

| Analytische Verfahren<br>Analytical Procedures              |   | Anforderung<br>Requirement                    | Ergebnis<br>Result               |    |
|---|---|---|----------------------------------|----|
| visuelle Kontrolle<br>visual inspection                     | Cap color   | blue  | confirmed                        | OK |
|   | Vial type   | clear glass vial                              | 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 |
|   | Appearance before reconstitution                    | buff colored plug of lyophilized material     | confirmed                        | OK |
|   | Appearance after reconstitution                     | buff colored liquid without visible particles | confirmed                        | OK |
| Virologie / Virology  | HBsAg / HBsAg<br>HIV-Ak / HIV-Ab<br>HCV-AK / HCV-Ab | Negative<br>Negative<br>Negative              | Negative<br>Negative<br>Negative | OK |
| The testing methods applied were FDA-approved or CE marked. |   |   |                                  |    |
| Kontrollwiederfindung<br>FIX am Ceveron® Alpha              | Control N<br>LOT 1P31C00                            | 87.8 - 146.3 %                                | 133.7 %                          | OK |
| Recovery of controls<br>FIX on Ceveron® Alpha               | Control A<br>LOT 3P23C00                            | 20.3 - 33.8 %                                 | 25.8 %                           | OK |

Durchgeführt von  
Prepared by

Stefan BRUCKBERGER

09. SEP. 2024

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Approved by

Kavdrim NASUFI

10. SEP. 2024

Datum / Date:



ANALYSENZERTIFIKAT  
CERTIFICATE OF ANALYSIS

DQ1Z00AZ

TECHNOTHROMBIN® TGA Control High 5x1mL

REF 5006320

LOT 1Z41C00.02

⌚ 2025-02-28

| Inhalt<br>Content | Reagenz<br>Reagent | LOT     | ⌚          |
|-------------------|--------------------|---------|------------|
| 5x1mL             | TGA Control High   | 1Z41C00 | 2025-02-28 |

| Analytische Prozedur<br>Analytical Procedure  | Anforderung<br>Requirement                       | Ergebnis<br>Result |          |
|---|--|--------------------|----------|
| Kontrollwiederfindung<br>Recovery of controls | TGA RC High<br>(nM Peak Thrombin)<br>LOT 7F21C01 | 332 - 553          | 446.4 OK |
|   | TGA RC Low<br>(nM Peak Thrombin)<br>LOT 7D31C01  | 269 - 448          | 337.1 OK |

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Fikret NASUFI *Fikret Nasufi*

01. AUG. 2024

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Approved by

Michael KAFKA *Michael Kafka*

02. AUG. 2024

Datum / Date:



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4K00.03  
Att.03  
4K32C0D.07

## Fitzgerald Trait Plasma 2x1 ml

REF      5204006-RUO  
LOT      4K32C0D.07  
      2025-08-31

| Analytische Verfahren<br>Analytical Procedures              | Anforderung<br>Requirement                          | Ergebnis<br>Result                        |              |
|---|---|---|--------------|
| visuelle Kontrolle<br>visual inspection                     | Cap color   | blue                                      | confirmed OK |
|   | Vial type   | clear glass vial                          | 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 |
|   | Appearance before reconstitution                    | buff colored plug of lyophilized material | confirmed OK |
|   | Appearance after reconstitution                     | buff colored liquid                       | confirmed OK |
| Virologie / Virology  | HBsAg / HBsAg<br>HIV-Ak / HIV-Ab<br>HCV-AK / HCV-Ab | Negative<br>Negative<br>Negative          | OK           |
| The testing methods applied were FDA-approved or CE marked. |   |   |              |
| Kontrollwiederfindung<br>HMWK am Ceveron® alpha             | <b>Control N</b><br>LOT 1P31C00                     | 88.5 - 147.5 %                            | 112.4 % OK   |
| Recovery of controls<br>HMWK on Ceveron® alpha              | <b>Control A</b><br>LOT 3P23C00                     | 42.0 - 70.0 %                             | 53.8 % OK    |

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*Stefan BRUCKBERGER*

09. SEP. 2024

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Approved by

*Lavdrim WASUFI*

10. SEP. 2024

Datum / Date:



ANALYSENZERTIFIKAT  
CERTIFICATE OF ANALYSIS

DQREL0AZ

LOT REL21C1.02

t-PA protein 100µg

REF TC41072



2023-05-02

LOT REL21C1.02



2025-05-31

| Analytische Verfahren<br>Analytical Procedure    | Anforderung<br>Requirement | Ergebnis<br>Result |    |
|--|----------------------------|--------------------|----|
| Antigen Konzentration /<br>Antigen concentration | ≥100 µg/mL                 | 103.7              | OK |

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Michael KAFKA

01. MRZ. 2024

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01. MRZ. 2024

Datum / Date:

**CERTIFICATE OF ANALYSIS**  
**Coagulation Control N 5x1 mL**



Attachment 04      DQ1P00.03

1P31C01.02

Temp.: TF0326.07

REF      5020040-RUO  
 LOT      1P31C01.02  
      2026-06-30

| Analytical Procedures                                       |   | Requirement                               | Result                           |    |
|---|---|---|----------------------------------|----|
| visual inspection   | Cap color   | red                                       | confirmed                        | OK |
|   | Vial type   | clear glass vial                          | 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 |
|   | Appearance before reconstitution                    | buff colored plug of lyophilized material | confirmed                        | OK |
|   | Appearance after reconstitution                     | amber colored liquid                      | confirmed                        | OK |
| Virology  | HBsAg / HBsAg<br>HIV-Ak / HIV-Ab<br>HCV-AK / HCV-Ab | Negative<br>Negative<br>Negative          | Negative<br>Negative<br>Negative | OK |
| The testing methods applied were FDA-approved or CE marked. |   |   |                                  |    |
| Recovery of controls  | <b>Siron LS</b>                                     | 20.1 - 27.3 sec                           | 24.1 sec                         | OK |

Prepared by

Stefan BRUCKBERGER

26. JUNI 2024

Date


Approved by

Maylis BAUSCHER

27. JUNI 2024

Date





|   |   |          |
|---|---|----------|
|  | <b>ANALYSENZERTIFIKAT<br/>CERTIFICATE OF ANALYSIS</b> | DQ9P00AZ |
|---|---|----------|

## TECHNOTHROMBIN® TGA BUF 5x3 mL

REF 5006360

LOT 9P21C01.01

 2025-04-30

| Inhalt<br>Content | Reagenz<br>Reagent | LOT     |  |
|-------------------|--------------------|---------|---|
| 5 x 3 mL          | TGA Buffer         | 9P21C01 | 2025-04-30  |

| Analytische Prozedur<br>Analytical Procedure                                 | Anforderung<br>Requirement  | Ergebnis<br>Result         |           |       |    |
|--|---|----------------------------|-----------|-------|----|
|  |   |                            |           |       |    |
| Verwendbarkeit / usability<br><br>Gerät / Analyzer:<br>Biotek Reader: 197091 | Regression der<br>Bezugskurve /<br>regression of the<br>calibration curve | $\geq 0.99$                | 0.99      | OK    |    |
| Kontrollwiederfindung<br>Recovery of controls                                | TGA Control High<br>(nM Peak Thrombin)<br>LOT 1Z24C00                     | TGA RC High<br>LOT 7F21C00 | 407 - 679 | 459.4 | OK |
|  | TGA Control Low<br>(nM Peak Thrombin)<br>LOT 2823C00                      | TGA RC High<br>LOT 7F21C00 | 127 - 211 | 139.4 | OK |

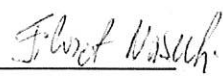
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20. APR. 2023

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