



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ4K00.03

Att.03

4K06C0D.04

Fitzgerald Trait Plasma 2x1 ml

| | |
|-----|-------------|
| REF | 5204006-RUO |
| LOT | 4K06C0D.04 |
| ⌚ | 2022-09-30 |

| Analytische Verfahren Analytical Procedures | | Anforderung Requirement | Ergebnis Result | |
|---|--|---|----------------------------------|----|
| visuelle Kontrolle 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 HIV-Ak / HIV-Ab HCV-AK / HCV-Ab The testing methods applied were FDA-approved or CE marked. | Negative Negative Negative | Negative Negative Negative | OK |
| Kontrollwiederfindung HMWK am Ceveron® alpha | Control N LOT 1P02C01 | 60.0 - 100.0 % | 81.3 % | OK |
| Recovery of controls HMWK on Ceveron® alpha | Control A LOT 3P91B01 | 19.5 - 32.5 % | 29.3 % | OK |

Durchgeführt von
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29. APR. 2021

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