



ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS

DQ0T00AZ

TECHNOTHROMBIN[®] TGA Kit 3x16 T.

REF 5006010

LOT 0T01C00.01

2021-01-31

Inhalt Content	Reagenz Reagent	LOT	
1x3mL	TGA CAL BUF	9P91B00	2021-05-31
3x1.5mL	TGA SUB	8F01C00	2022-02-28
1x0.5mL	TGA RC Low	7D01C00	2022-02-28
1x0.5mL	TGA RC High	7F92B00	2021-05-31
1x1.5mL	TGA RD	7G91B00	2021-04-30
1x0.5mL	TGA CAL	5T02C	2022-03-31
1x1mL	TGA Control High	1Z01C00	2021-01-31
1x1mL	TGA Control Low	2801C00	2021-01-31

Analytische Prozedur Analytical Procedure		Anforderung Requirement	Ergebnis Result	
Kontrollwiederfindung RC Low	TGA Control High (nM Peak Thrombin) LOT 1Z01C00	253 – 421	280.8	OK
Recovery of controls RC Low	TGA Control Low (nM Peak Thrombin) LOT 2801C00	164 – 274	218.0	OK
Kontrollwiederfindung RC High	TGA Control High (nM Peak Thrombin) LOT 1Z01C00	435 – 725	698.3	OK
Recovery of controls RC High	TGA Control Low (nM Peak Thrombin) LOT 2801C00	225 – 375	327.9	OK
Kontrollwiederfindung RD	TGA Control High (nM Peak Thrombin) LOT 1Z01C00	381 – 635	555.1	OK
Recovery of controls RD	TGA Control Low (nM Peak Thrombin) LOT 2801C00	440 - 734	634.4	OK



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Durchführung von
Prepared by

Fikret NASUFI *Fikret Nasufi*

14. APR. 2020

Datum / Date:

Freigabe von
Approved by

Michael KAFKA *[Signature]*

15. APR. 2020

Datum / Date: