



ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS

DQ0T00AZ

TECHNOTHROMBIN[®] TGA Kit 3x16 T.

REF 5006010

LOT 0T66B00.01

⌚ 30-Sep-2017

Inhalt Content	Reagenz Reagent	LOT	⌚
1x3mL	TGA buffer	9P31B02	31-Jul-2018
3x1.5mL	TGA substrat	8F52B00	31-Oct-2017
1x1.5mL	TGA reagent RD	7G61B00	30-Jun-2018
1x0.5mL	TGA reagent RC Low	7D62B00	31-May-2018
1x0.5mL	TGA reagent RC High	7F61B00	28-Feb-2018
1x0.5mL	TGA Thrombin Calibrator	5T61B	31-Mar-2018
1x1mL	TGA Control High	1B52B00	30-Sep-2017
1x1mL	TGA Control Low	2B61B03	30-Sep-2017

Analytische Prozedur Analytical Procedure		Anforderung Requirement	Ergebnis Result	
Kontrollwiederfindung RC High	TGA Control High (nM Peak Thrombin) LOT 1B52B00)	140 – 469	291.3	OK
Recovery of controls RC High	TGA Control Low (nM Peak Thrombin) LOT 2B61B03	75 – 212	159.9	OK
Kontrollwiederfindung RC Low	TGA Control High (nM Peak Thrombin) LOT 1B52B00)	115 – 359	250.8	OK
Recovery of controls RC Low	TGA Control Low (nM Peak Thrombin) LOT 2B61B03	42 - 103	66.8	OK
Kontrollwiederfindung RD	TGA Control High (nM Peak Thrombin) LOT 1B52B00)	341 – 481	449.2	OK
Recovery of controls RD	TGA Control Low (nM Peak Thrombin) LOT 2B61B03	228 – 347	262.5	OK



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Durchführung von
Prepared by

Fikret NASUFI *Fikret Nasufi*

05. AUG. 2016
Datum / Date:

Freigabe von
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08. AUG. 2016
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