

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ0T00AZ
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TECHNOTHROMBIN[®] TGA Kit 3x16 T.

REF 5006010
LOT 0T62B00.01
 30-Nov-2016

Inhalt Content	Reagenz Reagent	LOT	
1x3mL	TGA buffer	9P31B01	30-Apr-2017
3x1.5mL	TGA substrat	8F52B00	31-Oct-2017
1x1.5mL	TGA reagent RD	7G51B00	31-Jan-2017
1x0.5mL	TGA reagent RC Low	7D51B00	28-Feb-2017
1x0.5mL	TGA reagent RC High	7F61B00	28-Feb-2018
1x0.5mL	TGA Thrombin Calibrator	5T41B	30-Nov-2016
1x1mL	TGA Control High	1B52B00	30-Sep-2017
1x1mL	TGA Control Low	2B61B01	28-Feb-2017

Analytische Prozedur Analytical Procedure		Anforderung Requirement	Ergebnis Result	
Kontrollwiederfindung RC High	TGA Control High (nM Peak Thrombin) LOT 1B52B00)	140 – 469	385.6	OK
Recovery of controls RC High	TGA Control Low (nM Peak Thrombin) LOT 2B61B01	75 – 212	201.8	OK
Kontrollwiederfindung RC Low	TGA Control High (nM Peak Thrombin) LOT 1B52B00)	115 – 359	272.9	OK
Recovery of controls RC Low	TGA Control Low (nM Peak Thrombin) LOT 2B61B01	42 - 103	97.6	OK
Kontrollwiederfindung RD	TGA Control High (nM Peak Thrombin) LOT 1B52B00)	341 – 481	445.7	OK
Recovery of controls RD	TGA Control Low (nM Peak Thrombin) LOT 2B61B01	228 – 347	271.1	OK



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Durchführung von
Prepared by

Fikret NASUFI *Fikret Nasufi*

26-Feb-2016
Datum / Date:

Freigabe von
Approved by

Michael KAFKA *Michael Kafka*

26-Feb-2016
Datum / Date: