



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ0D00AZ

CEVERON TGA Cal Set f.Ceveron

REF 5006347

LOT 0D52B00.02

⌚ 30-Nov-2016

Inhalt Content	Reagenz Reagent	LOT	⌚
1 x 3 mL	TGA buffer	9P31B01	30-Apr-2017
1 x 0.5mL	TGA Thrombin Calibrator	5T41B	30-Nov-2016
1 x 1 mL	TGA Reaction Buffer f.Ceveron	9K51B	30-Apr-2017

Analytische Prozedur Analytical Procedure		Anforderung Requirement	Ergebnis Result	
Kalibrierung / Calibration gegen / against WHO 01/580		800-900 nM	841	OK
Verwendbarkeit / usability Gerät / Analyzer: Ceveron:10091	Regression der Bezugskurve / regression of the calibration curve	≥ 0.990	1.0	OK
Kontrollwiederfindung Recovery of controls TGA RCH f.Ceveron 7F41B	TGA Control High (nM Peak Thrombin) LOT 1B41B00)	188 – 350	253.6	OK
	TGA Control High (Lag time min) LOT 1B41B00)	1.5 – 2.7	2.4	OK
	TGA Control High (AUC) LOT 1B41B00)	2082 – 3866	2950.8	OK
Etiketten und Barcode Überprüfung Label and bar code Verification				OK



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Durchführung von
Prepared by

Fikret NASUFI

10-Sep-2015

Datum / Date:

Freigabe von
Approved by

[Signature]

10-SEP-2015

Datum / Date:

Ceveron® alpha

S. SCHWINGENSCHLÖGL

10-Sep-2015

Datum / Date: