



ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS


DQ7G00AZ


LOT 7G83A03

TECHNOTHROMBIN[®] TGA Reagent RD

REF 5006220

LOT 7G83A03

 07 - Oct - 2008

 30 - Jun - 2015

Analytische Verfahren Analytical Procedure		Anforderung Requirement	Ergebnis Result	
pH		6.5 – 7.5	7.0	OK
Restfeuchte Residual moisture		≤1%	0.070%	OK
Homogenität Homogeneity	TGA Control High (nM Peak Thrombin)	CV ≤ 5%	3.1%	OK
Lösungsstabilität 8 Stunden bei RT Reconstituted stability 8 hours at RT	Technotrombin TGA (RFU)	0.85 – 1.15	0.97	OK
Kontrollwiederfindung Recovery of controls	TGA Control High (nM Peak Thrombin) LOT 1B12B01	166 – 308	252.4	OK
	TGA Control Low (nM Peak Thrombin) LOT 2B02BRV	129 – 239	180.9	OK
Lagerstabilität 4 Wochen bei 37°C Storage stability 4 weeks at 37°C	TGA Control High (nM Peak Thrombin) LOT 1B12B01	0.90 – 1.10	1.08	OK

Durchführung von
Prepared by

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27. Jun - 2013
Datum / Date:

Freigabe von
Approved by

Harald SEVCIK 

16. JULI 2013
Datum / Date: