

	<b>ANALYSENZERTIFIKAT</b> <b>CERTIFICATE OF ANALYSIS</b>	DQ7G00AZ  <b>LOT</b> 7G51B00
---	---	------------------------------------

## TECHNOTHROMBIN<sup>®</sup> TGA Reagent RD

**REF**      5006148  
**LOT**      7G51B00  
      30-Jan-2015  
      31-Jan-2017

<b>Analytische Verfahren</b> <b>Analytical Procedure</b>		<b>Anforderung</b> <b>Requirement</b>	<b>Ergebnis</b> <b>Result</b>	
pH		6.5 – 7.5	6.8	OK
Restfeuchte Residual moisture		≤1%	0.95 %	OK
Homogenität Homogeneity	TGA Control High (nM Peak Thrombin) <b>LOT</b> 1B41B00	CV ≤ 5%	4.3 %	OK
Lösungsstabilität 8 Stunden bei RT	TGA Control High (nM Peak Thrombin) <b>LOT</b> 1B41B00	< 10%	1.3 %	OK
Reconstituted stability 8 hours at RT	TGA Control Low (nM Peak Thrombin) <b>LOT</b> 2B43B00	< 10%	2.6 %	OK
Kontrollwiederfindung	TGA Control High (nM Peak Thrombin) <b>LOT</b> 1B41B00	161 – 299	192.8	OK
Recovery of controls	TGA Control Low (nM Peak Thrombin) <b>LOT</b> 2B43B00	239 – 443	250.3	OK
Lagerstabilität 4 Wochen bei 37°C  Storage stability 4 weeks at 37°C	TGA Control High (nM Peak Thrombin) <b>LOT</b> 1B41B00	< 10%	0.7	OK



ANALYSENZERTIFIKAT  
CERTIFICATE OF ANALYSIS

DQ7G00AZ

LOT 7G51B00

Durchführung von  
Prepared by

Fikret NASUFI *Fikret Nasufi*

16-MAR-2015  
Datum / Date:

Freigabe von  
Approved by

Michael RIHA *Michael Riha*

16 MAR-2015  
Datum / Date: