



ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS

DQ7F00AZ.02.

TECHNOTHROMBIN[®] TGA Reagenz C high (RCH)
TECHNOTHROMBIN[®] TGA Reagent C high (RCH)

REF 50 062 16 (50x0,5ml)

REF 50 062 14 (5x0,5ml)

REF 50 061 45 (HFP)


LOT 7F23B00

Herstelldatum /
Date of manufacturing 17-Dec-2012



30-Jun-2015

Test	Spezifikation / specification	Ergebnis / result											
Restfeuchte % / Residual Humidity %	≤1%	0.06%											
pH Wert / pH-Value	7.0 – 7.6	7.2											
Homogenität / Homogeneity VK / CV% TGA Control High (nM Thrombin)	≤ 5%	2.2%											
Lösungsstabilität / Stability of solution Abweichung: Unbelastet / 8 Stunden Deviation: Unstressed / 8 hours	TGA Control High (nM Thrombin) Abw / Dev 15%	<table border="1"> <tr> <td>Unbelastet unstressed</td> <td>8 Stunden 8 hours</td> </tr> <tr> <td>499.2</td> <td>492.1</td> </tr> </table>	Unbelastet unstressed	8 Stunden 8 hours	499.2	492.1							
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RC Low Verwendbarkeit / RC Low usability Abweichung / Deviation Gerät / Analyzer: Biotek Reader	<table border="1"> <tr> <td>TGA Control High (nM Thrombin) Lot:1B12B00</td> <td> <table border="1"> <tr> <td>Richtwert / expected value</td> <td>316,0 - 586,0</td> </tr> <tr> <td>Aktivität / Activity</td> <td>479.6</td> </tr> </table> </td> </tr> <tr> <td>TGA Control Low (nM Thrombin) Lot:2B02BRV</td> <td> <table border="1"> <tr> <td>Richtwert / expected value</td> <td>55,0 – 101,0</td> </tr> <tr> <td>Aktivität / Activity</td> <td>71.7</td> </tr> </table> </td> </tr> </table>	TGA Control High (nM Thrombin) Lot:1B12B00	<table border="1"> <tr> <td>Richtwert / expected value</td> <td>316,0 - 586,0</td> </tr> <tr> <td>Aktivität / Activity</td> <td>479.6</td> </tr> </table>	Richtwert / expected value	316,0 - 586,0	Aktivität / Activity	479.6	TGA Control Low (nM Thrombin) Lot:2B02BRV	<table border="1"> <tr> <td>Richtwert / expected value</td> <td>55,0 – 101,0</td> </tr> <tr> <td>Aktivität / Activity</td> <td>71.7</td> </tr> </table>	Richtwert / expected value	55,0 – 101,0	Aktivität / Activity	71.7
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Lagerstabilität / Storage stability Abweichung: Unbelastet / 4 Woche Deviation: Unstressed / 4 weeks	TGA Control High (nM Thrombin) Ratio: 0,80 – 1,20	1.02											

	<p style="text-align: center;">ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS</p>	<p style="text-align: right;">DQ7F00AZ.02.</p>
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Erstellt / created: E.Tschokert

Unterschrift / signature:  Datum / date: 15-Jan-2013

Charge freigegeben / batch is released: Ja / yes Nein / no

Freigegeben / released:

Unterschrift / signature:  Datum / date: 15-JAN 2013

Ceveron® Softwear Eingabe / Ceveron® Software input :

Ja / yes Nein / no

Unterschrift / signature:  Datum / date: 15-Jan-2013