



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ0T00AZ

## TECHNOTHROMBIN TGA(Kit)

**REF** 5006010

**LOT** 0T65000

31.12.2007

### 1.Packungsinhalt / Package content

<b>Inhalt/ Content</b>	<b>Reagenz/reagent</b>	<b>LOT</b>	<b></b>	
1 x 3 ml	TGA buffer	9P51002	31.12.2007	<input checked="" type="checkbox"/> JA/YES <input type="checkbox"/> NEIN/NO
3 x 1,5 ml	TGA substrat	8F62000	31.12.2007	<input checked="" type="checkbox"/> JA/YES <input type="checkbox"/> NEIN/NO
1 x 0,5 ml	TGA reagent RB	7C64000	31.12.2007	<input checked="" type="checkbox"/> JA/YES <input type="checkbox"/> NEIN/NO
1 x 0,5 ml	TGA reagent RC Low	7D63000	31.12.2007	<input checked="" type="checkbox"/> JA/YES <input type="checkbox"/> NEIN/NO
1 x 0,5 ml	TGA reagent RC High	7F63000	31.12.2007	<input checked="" type="checkbox"/> JA/YES <input type="checkbox"/> NEIN/NO
1 x 0,5ml	TGA Thrombin Calibrator	5T55001	31.12.2007	<input checked="" type="checkbox"/> JA/YES <input type="checkbox"/> NEIN/NO
1 x 1 ml	TGA Control 1	1R31002	31.12.2007	<input checked="" type="checkbox"/> JA/YES <input type="checkbox"/> NEIN/NO
1 x 1 ml	TGA Control 2	1B62000	31.12.2007	<input checked="" type="checkbox"/> JA/YES <input type="checkbox"/> NEIN/NO
1 x 1 ml	TGA Control 3	2B53000	30.06.2008	<input checked="" type="checkbox"/> JA/YES <input type="checkbox"/> NEIN/NO

### **Freigabekriterium / Requirements:**

Die Packung muss 1 x 3 ml TGA Puffer, 3 x 1,5ml TGA Substrat, 1 x 0,5 ml TGA reagent RB, 1x 0,5ml TGA reagent RC Low, 1 x 0,5ml TGA reagent RC High, 1 x 0,5 ml TGA Thrombin standard 1 x 1ml TGA Control 1, 1 x 1ml TGA Control 2, 1 x 1ml Control 3 enthalten.

The package should contain 1 x 3 ml TGA buffer, 3 x 1,5ml TGA Substrat, 1 x 0,5 ml TGA reagent RB, 1x 0,5ml TGA reagent RC Low, 1 x 0,5ml TGA reagent RC High, 1 x 0,5 ml TGA Thrombin standard 1 x 1ml TGA Control 1, 1 x 1ml TGA Control 2, 1 x 1ml TGA Control 3.

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## 2. Verwendbarkeit / Usability

Ergebnis / result

REF	LOT	Peak thrombin nM	
TECHNOTHROMBIN® TGA C1 5006170	1R31002	RB RC Low	237
		RC High	393
TECHNOTHROMBIN® TGA C2 5006160	1B62000	RB RC Low	354
		RC High	478
TECHNOTHROMBIN® TGA C3 5006180	2B53000	RB RC Low	-
		RC High	60

Freigabekriterium/ Release criteria

REF	LOT	Peak thrombin nM	
TECHNOTHROMBIN® TGA C1 5006170	1R31002	RB RC Low	226 (170-283)
		RC High	360 (270-450)
TECHNOTHROMBIN® TGA C2 5006160	1B62000	RB RC Low	338 (253-422)
		RC High	472 (355-591)
TECHNOTHROMBIN® TGA C3 5006180	2B41000	RB RC Low	-
		RC High	69 (52-86)

Der nM Peak Wert der Kontrollen muss innerhalb des angegebenen Vertrauensbereiches liegen.

The nM peak thrombin value of the controls must be within the confidential range given above.

**Der TECHNOTHROMBIN TGA Kit, LOT 0T65000 wird freigegeben.**

**The TECHNOTHROMBIN TGA Kit, LOT 0T65000, is released.**

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