

	<b>ANALYSENZERTIFIKAT</b> <b>CERTIFICATE OF ANALYSIS</b>	DQxRT0.01
		Alt.22
		7QT81B0.01

## TECHNOZYM® ADAMTS-13 Control Set 2x0.5 mL

REF	5450563
LOT	7QT81B0.01
	2020-02-29

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	0.5mL	HFP: RY ADAMTS-13 Antigen High Control	RRY81B0	2020-02-29
1x	0.5mL	HFP: RZ ADAMTS-13 Antigen Low Control	RRZ81B0	2020-02-29

Analytische Verfahren Analytical Procedures		Anforderung Requirement			Ergebnis Result	
visuelle Kontrolle visual inspection	Content	according to packaging SOP			confirmed	OK
	Vial label	according to packaging SOP			confirmed	OK
	Box label	according to packaging SOP			confirmed	OK
	Package insert	present			confirmed	OK
	Batch table	present			confirmed	OK
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Antigen High Control (Activity) LOT RRY81B0	0.44	-	0.74 IU/mL	0.57 IU/mL	OK
	ADAMTS-13 Antigen Low Control (Activity) LOT RRZ81B0	0.10	-	0.22 IU/mL	0.15 IU/mL	OK
	ADAMTS-13 Antigen High Control (Antigen) LOT RRY81B0	0.53	-	0.89 IU/mL	0.63 IU/mL	OK
	ADAMTS-13 Antigen Low Control (Antigen) LOT RRZ81B0	0.11	-	0.25 IU/mL	0.14 IU/mL	OK

Durchgeführt von  
Prepared by

Fikret NASUFI *Fikret Nasufi*

24. SEP. 2018

Datum / Date:

Freigabe von  
Approved by

Michael KAFKA *[Signature]*

24. SEP. 2018

Datum / Date: