
	<b>ANALYSENZERTIFIKAT</b> <b>CERTIFICATE OF ANALYSIS</b>	DQRR00.02  Att.04  RR22C00.02
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## TECHNOZYM ADAMTS-13 Antigen ELISA 96T.

REF	5450601-RUO
LOT	RR22C00.02
	2023-08-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	
1x	-	HFP: RS ADAMTS-13 Ag ELISA Platte 96T.	RRS21C0	2024-02-29
1x	0.3 mL	HFP: QV ADAMTS-13 Conjugate	RQV12C0	2023-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 1	1RT11C0	2023-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 2	2RT11C0	2023-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 3	3RT11C0	2023-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 4	4RT11C0	2023-08-31
1x	0.5 mL	HFP: RT ADAMTS-13 Antigen Calibrator 5	5RT11C0	2023-08-31
1x	0.5 mL	HFP: RY ADAMTS-13 Antigen High Control	RRY11C0	2023-08-31
1x	0.5 mL	HFP: RZ ADAMTS-13 Antigen Low Control	RRZ11C0	2023-08-31
1x	80 mL	HFP: NA wash buffer + thimerosal	RNA21C0	2024-03-31
1x	90 mL	HFP: NB Incubation buffer	RNB14C0	2023-12-31
1x	12 mL	HFP: KK Stop solution for TMB	RKK21C0	2024-02-29
1x	12 mL	HFP: KN TMB Substrate	RKN21C0	2024-02-29

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
Verwendbarkeit Usability	deltaOD Ca1-Ca5	≥ 0.7	1.1	OK
Kontrollwiederfindung Recovery of controls	<b>High Control</b> LOT RRY11C0	0.50 - 0.83 IU/mL	0.61 IU/mL	OK
	<b>Low Control</b> LOT RRZ11C0	0.13 - 0.31 IU/mL	0.17 IU/mL	OK



**ANALYSENZERTIFIKAT  
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Durchgeführt von  
Prepared by

**Fikret NASUFI** *Fikret Nasufi*

**22. MRZ. 2022**

Datum / Date:

Freigabe von  
Approved by

**Michael KAFKA** *Michael Kafka*

**23. MRZ. 2022**

Datum / Date: