

TECHNOZYM® ADAMTS13 Calibrator Set 5x0.5 mL

REF 5450561
LOT 6QT01C0.01
2021-08-31

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	🕒
1x	0.5mL	HFP: RT ADAMTS13 Antigen Calibrator 1	1RT91B0	2021-08-31
1x	0.5mL	HFP: RT ADAMTS13 Antigen Calibrator 2	2RT91B0	2021-08-31
1x	0.5mL	HFP: RT ADAMTS13 Antigen Calibrator 3	3RT91B0	2021-08-31
1x	0.5mL	HFP: RT ADAMTS13 Antigen Calibrator 4	4RT91B0	2021-08-31
1x	0.5mL	HFP: RT ADAMTS13 Antigen Calibrator 5	5RT91B0	2021-08-31

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	ΔRFU/min Activity (Cal 1 - Cal 5)	≥ 200 RFU/min	341 RFU/min	OK
	ADAMTS13 Antigen High Control (Activity) LOT RRY91B0	0.55 - 0.91 IU/mL	0.65 IU/mL	OK
	ADAMTS13 Antigen Low Control (Activity) LOT RRZ91B0	0.12 - 0.28 IU/mL	0.15 IU/mL	OK
	ΔRFU Antigen (Cal 1 - Cal 5)	≥ 200 RFU	341 RFU	OK
	ADAMTS13 Antigen High Control (Antigen) LOT RRY91B0	0.53 - 0.89 IU/mL	0.72 IU/mL	OK
	ADAMTS13 Antigen Low Control (Antigen) LOT RRZ91B0	0.13 - 0.29 IU/mL	0.22 IU/mL	OK

Durchgeführt von
Prepared by

Michael KAFKA

10. FEB. 2020

Datum / Date:

Freigabe von
Approved by

Fikret NASUFI

11. FEB. 2020

Datum / Date: