

# Technofluor ADAMTS13:Act 0 CAL



Attachment 07 DQFA00.01

Temp.: TPI0326.06

REF	5800102-RUO
LOT	FAC21C0.02
⏰	2024-07-31

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	green	confirmed	OK
	Vial type	clear glass vial	confirmed	OK
	Vial label	according to packaging SOP	confirmed	OK
	Vial barcode	according to packaging SOP	confirmed	OK
	Box label	according to packaging SOP	confirmed	OK
	Box barcode	according to packaging SOP	confirmed	OK
	Ceveron s100 barcode	functional	functional	OK
	Package insert	present	confirmed	OK
	Batch table	present	confirmed	OK
	Appearance before reconstitution	buff colored plug of lyophilized material	confirmed	OK
Appearance after reconstitution	amber colored liquid	confirmed	OK	
Virology	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab  The testing methods applied were FDA-approved or CE marked.	Negative Negative Negative	Negative Negative Negative	OK
Recovery of controls	<b>Control N</b> LOT 1P11C00	0.67 - 1.11 IU/mL	0.99 IU/mL	OK
	<b>Control A</b> LOT 3P22C00	0.36 - 0.60 IU/mL	0.49 IU/mL	OK

Prepared by

Michael KAFKA

01. AUG. 2022

Date

Approved by

Christoph ENNE

02. AUG. 2022

Date