

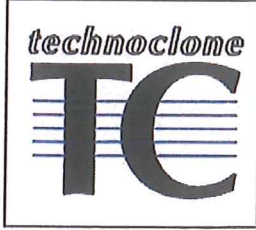
	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	8PT82BM
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HFP: ECAT ADAMTS-13 INH Plasma medium

REF	5450446	LOT	8PT82BM
	2018-03-09		2020-03-31

Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result	
Type of material		Plasma	Plasma	OK
Reconstituted volume		= 0.5 mL	0.5 mL	OK
Virologie / Virology HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.		Negative Negative Negative	Negative Negative Negative	OK
Homogenität n=10 Homogeneity n=10 according to ISO13528:2005 Annex B *LOT-size too small for Intra-part of homogeneity testing	Intra-part	ADAMTS-13 INH ELISA	≤ 7.50 %	n.a. % *
	Inter-part	ADAMTS-13 INH ELISA	≤ 7.50 %	21.20 % ***
Richtwert n=10 Expected value n=10	ADAMTS-13 INH ELISA		7.5 - 12.5 U/mL	11.0 U/mL
			CV ≤ 7.5 %	26.9 %
Lösungsstabilität n=2, 2 Stunden bei 18-25°C In use stability n=2, 2 hours at 18-25°C	ADAMTS-13 INH ELISA		≤ 7.5 %	4.8 %
			mean value at baseline	8.1
		mean value after stressing	7.7	OK
Lagerstabilität n=2, 1 Woche bei 37°C Storage Stability n=2, 1 week at 37°C	ADAMTS-13 INH ELISA		≤ 7.5 %	1.7 %
			mean value at baseline	11.0
			mean value after stressing	11.2

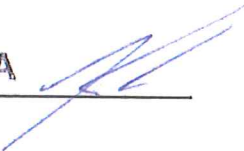
Rev.01
 ***) Sonderfreigabe ***) Special Release



**ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS**

8PT82BM

Durchgeführt von
Prepared by

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04. APR. 2018

Datum / Date:

Freigabe von
Approved by

Fikret NASUFI 

04. APR. 2018

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