



**ANALYSENZERTIFIKAT
CERTIFICATE OF ANALYSIS**

DQ8PT0AZ

LOT 8PT62B0L

HFP: Adamts 13 INH ECAT 0.5mL low

REF 5450443



08-Feb-2016

LOT 8PT62B0L



28-Feb-2018

Analytische Verfahren Analytical Procedure	Anforderung Requirement	Ergebnis Result	
Type of material	-	Plasma	OK
Volume	-	0.5mL	OK
Kalibrierung / Calibration gegen/against n = 10 internal calibration set	2.5 – 5.0 U/mL	3.26	OK
	CV ≤ 40%	14.5	OK
Homogenität / Homogeneity n = 10 according to ISO13528:2005 Annex B	CV ≤ 40%	14.5	OK
HBsAg HIV-AK HCV-AK The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.	negative / negativ negative / negativ negative / negativ	Ja / yes	OK
Lösungsstabilität 2 Stunden bei Raumtemperatur n = 5	CV ≤ 20%	16.1	OK
	mean value at baseline	3.47	OK
	mean after stressing	4.12	OK
Lagerstabilität 1 Woche bei 37°C n = 5	CV ≤ 20%	8.4	OK
	mean value at baseline	3.47	OK
	mean after stressing	4.44	OK

Durchführung von
Prepared by

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23-Feb-2016
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25-FEB-2016
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