

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ8PT0AZ LOT 8PT61B0H
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HFP: Adamts 13 INH ECAT 0.5mL high

REF 5450445



08-Feb-2016

LOT 8PT61B0H



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	7.5 – 10.0 U/mL CV ≤ 20%	8.95 5.95	OK OK
Homogenität / Homogeneity n = 10 according to ISO13528:2005 Annex B	CV ≤ 20%	5.95	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% mean value at baseline	8.6 8.71	OK OK
Solution stability 2 hours at roomtemperature	mean after stressing	8.91	OK
Lagerstabilität 1 Woche bei 37°C n = 5	CV ≤ 20% mean value at baseline	11.2 8.71	OK OK
Storage stability 1 week at 37°C	mean after stressing	9.22	OK

Durchführung von
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23-Feb-2016
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25-Feb-2016
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