

	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ8PT0AZ LOT 8PT63BM
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HFP: Adamts 13 INH ECAT 0.5mL medium

REF 5450446


23-Jun-2016

LOT 8PT63BM


30-Jun-2018

Analytische Verfahren Analytical Procedure	Anforderung Requirement	Ergebnis Result	
Type of material	Plasma	Plasma	OK
Volume	0.5 mL	0.5 mL	OK
Kalibrierung / Calibration gegen/against n = 10 internal calibration set	7.5 U/mL CV ≤ 20%	8.40 15.1	OK
Homogenität / Homogeneity n = 10 according to ISO13528:2005 Annex B	CV ≤ 20%	15.1	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 Solution stability 2 hours at roomtemperature	CV ≤ 20% mean value at baseline mean after stressing	6.39 7.81 8.3	OK
Lagerstabilität 1 Woche bei 37°C n = 5 Storage stability 1 week at 37°C	CV ≤ 20% mean value at baseline mean after stressing	6.58 7.81 8.21	OK

Durchführung von
Prepared by

Michael KAFKA

11-Jul-2016
Datum / Date:

Freigabe von
Approved by

Alessandro BENIGNI

11. JULI 2016
Datum / Date: