



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQ1R00AZ.01

LOT 1R51B01

## Coagulation Reference

REF 52 201 00

LOT 1R51B01

08-Oct-2012

28-Feb-2018

Analytische Verfahren Analytical Procedure		Anforderung Requirement	Ergebnis Result	
pH		7.0 – 7.8	7.6	OK
Restfeuchte Residual moisture		≤1%	0.03	OK
OD <sub>320nm</sub>		≤10	9.4	OK
Virologie Virology	HBsAg / HBsAg HIV-AK / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	Negative Negative Negative	OK
Homogenität Homogeneity		CV ≤ 3%	1.29	OK
Lösungsstabilität 5 Stunden bei RT  Reconstituted stability 5 hours at RT	Dapttin (sec) Change from storage at RT	0.90 – 1.10	0.95	OK
	Technoclot PT Plus (%) Change from storage at RT		1.03	OK
	Fibrinogen (g/L) Change from storage at RT		1.01	OK
Lagerstabilität 4 Wochen bei 37°C  Storage stability 4 weeks at 37°C	Siron (sec) Change from storage at 2-8°C	0.90 – 1.10	1.00	OK
	Technoclot PT Plus (%) Change from storage at 2-8°C		0.94	OK
	Fibrinogen (g/L) Change from storage at 2-8°C		1.05	OK

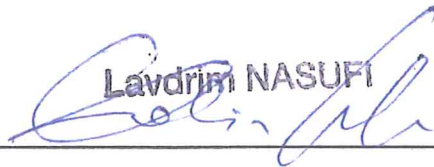


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