



# ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS


DQ3L00AZ.02

**LOT** 3L64B01

## AK Calibrant B 1mL

**REF** 5010006

**LOT** 3L64B01

 03-Aug-2016

 31-Oct-2019

Analytische Verfahren Analytical Procedure		Anforderung Requirement	Ergebnis Result		
pH		7.4 – 7.8	7.7	OK	
Restfeuchte Residual moisture		≤1%	0.46	OK	
OD <sub>320nm</sub>		≤20	7.4	OK	
Virologie Virology	HBsAg / HBsAg HIV-AK / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	Negative Negative Negative	OK	
Homogenität Homogeneity VK / CV	Intra-Tassen	Technoplastin HIS (%)	CV ≤ 3%	1.12	OK
		Technoplastin HIS (INR)	CV ≤ 3%		
	Inter-Tassen	Technoplastin HIS (%)	CV ≤ 3%	1.24	OK
		Technoplastin HIS (INR)	CV ≤ 3%	1.12	
Chargenspezifische Kalibrationswerte Lot specific calibration values		INR	2.25	OK	
Lösungsstabilität 4 Stunden bei RT  Reconstituted stability 4 hours at RT		Technoplastin HIS (%)	< 10%	5.8	OK
Lagerstabilität 5 Wochen bei 37°C  Storage stability 5 weeks at 37°C	Technoplastin HIS (%)		< 10%	3.6	OK
	Technoplastin HIS (INR)		< 10%	3.4	OK
	Siron LS (sec)		< 10%	4.3	OK



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**12. MAI 2017**

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