
	ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS	DQ1R00AZ.02.
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Coagulation Reference

REF	52 201 20 (50 x 1ml)
REF	52 201 10 (5 x 1ml)
REF	52 201 00 (HFP)
LOT	1R2EB00

Herstelldatum /
Date of manufacturing 15-Jun-2011

 30-Jun-2016

Test	Spezifikation / specification	Ergebnis / result						
Restfeuchte %	≤ 1 %	0.07 %						
pH Wert / pH-Value	7.4 – 7.8	7.7						
Trübungsmesswert / Measurement of turbidity	≤ 20	7.0						
HBsAg HIV-AK HCV-AK	Negativ / negative Negativ / negative Negativ / negative	Negativ / negative Negativ / negative Negativ / negative						
Homogenität / Homogeneity: TT: VK / CV% Coagulation Control N (sec)	≤ 3%	2.6%						
Lösungsstabilität / Stability of solution Abweichung: Unbelastet / 4 Stunden Deviation: Unstressed / 4 hours	aPTT (sec)	<table border="1" style="width: 100%; text-align: center;"> <tr> <td style="width: 50%;">Abw / Dev 10%</td> <td>Unbelastet unstressed</td> <td>4 Stunden 4 hours</td> </tr> <tr> <td></td> <td>31,4sec</td> <td>31,3sec</td> </tr> </table>	Abw / Dev 10%	Unbelastet unstressed	4 Stunden 4 hours		31,4sec	31,3sec
	Abw / Dev 10%	Unbelastet unstressed	4 Stunden 4 hours					
	31,4sec	31,3sec						
Thrombotest (%)	<table border="1" style="width: 100%; text-align: center;"> <tr> <td style="width: 50%;">Abw / Dev 20%</td> <td>Unbelastet unstressed</td> <td>4 Stunden 4 hours</td> </tr> <tr> <td></td> <td>80,8%</td> <td>89,0%</td> </tr> </table>	Abw / Dev 20%	Unbelastet unstressed	4 Stunden 4 hours		80,8%	89,0%	
Abw / Dev 20%	Unbelastet unstressed	4 Stunden 4 hours						
	80,8%	89,0%						
Lagerstabilität / 37°C Storage stability 37°C Abweichung: Unbelastet / 8 Woche Deviation: Unstressed / 8 weeks	aPTT (sec)	Ratio: 0.90 – 1.10 1.04						
	Thrombotest (%)	Ratio: 0.80 – 1.20 0.92						
	Factor VIII (1:5) (sec)	Ratio: 0.90 – 1.10 1.01						
Batch specific insert	yes	yes						

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Erstellt / created:

Unterschrift / signature:



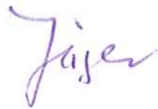
Datum / date: 04-Dec-2012

Charge freigegeben / batch is released: Ja / yes

Nein / no

Freigegeben / released:

Unterschrift / signature:



Datum / date: 04-Dec-2012

Ceveron® Software Eingabe / Ceveron® Software input :

Ja / yes

Nein / no

Unterschrift / signature:



Datum / date: 04-Dec-2012