

ANALYSIS CERTIFICATE

CEPHEN 5 - #CK515K/CK515L

Lot : F1600011

QC release: 22/02/2016

Expiration date : 2018-01-01

CK515K: 8 x 5ml CK515L: 12 x 5ml

Components	Volume	Exp. (months)	Internal Lot #	Lot #	Exp. date
Cephen 5	5 ml	24	F161100011	F161100011	2018-01-01

SAS

ANALYSIS CERTIFICATE

CEPHEN 5 - #CK515K/CK515L

Lot : F1600011

QC release:

22/02/2016

Expiration date : 2018-01-01

Analytical data	Specifications						
<p>1. <u>Batch reproducibility</u> (various vials tested) on normal plasma</p> <p style="text-align: right; margin-right: 100px;">N : 30 Mean CT : 30,7 Sec. CV : 2,7 %</p>	<p>N ≥ 10 ≤ 3 %</p>						
<p>2. <u>aPTT on normal citrated human plasmas</u></p> <p style="text-align: right; margin-right: 100px;">Instrument: STAR</p> <p style="text-align: right; margin-right: 100px;">N: 14 Mean CT : 30,3 Sec. SD: 1,8 Sec. Range: 28,1 - 34,3 Sec.</p>	<p>N ≥ 10 28 to 35 Sec. ≤ 3 Sec.</p>						
<p>3. <u>Aspect</u></p> <p style="text-align: center;">Clear, opalescent</p>	<p>Clear, Opalescent</p>						
<p>4. <u>Stability</u></p> <p style="text-align: center;"><i>Clotting time, on normal citrated human plasma</i></p> <p style="text-align: right; margin-right: 100px;">Instrument: MC10</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="width: 100px;"></td> <td style="text-align: center;">Stored</td> </tr> <tr> <td style="text-align: center;">1 week at RT</td> <td style="text-align: center;">30,6 Sec</td> </tr> <tr> <td style="text-align: center;">1 week at 2-8°C</td> <td style="text-align: center;">30,9 Sec</td> </tr> </table>		Stored	1 week at RT	30,6 Sec	1 week at 2-8°C	30,9 Sec	<p>ΔCT stored/Fresh ≤ 3 Sec.</p>
	Stored						
1 week at RT	30,6 Sec						
1 week at 2-8°C	30,9 Sec						

Comments :



PASSED IN COMPLIANCE

Date :

22/02/2016

QC Manager :

S. LECOURT

