

## ANALYSIS CERTIFICATE

**CEPHEN 1 - #CK511K**

**Lot : F1601247**

**QC release: 2017-01-27**

**Expiration date : 2018-11-25**

<b>Components</b>	<b>Volume (1mL)</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
Cephen 1	6 vials	24	F161E01247	2018-11-25

*SPS*

## ANALYSIS CERTIFICATE

**CEPHEN 1 - #CK511K**

**Lot : F1601247**

**QC release:**

**2017-01-27**

**Expiration date : 2018-11-25**

Analytical data	Specifications						
<p><b>1. <u>Batch reproducibility (various vials tested) on normal plasma</u></b></p> <p style="text-align: center;">N : 5            Mean CT : 27,4 Sec.            CV : 2,0 %</p>	<p>CV ≤ 3 %</p>						
<p><b>2. <u>aPTT on normal citrated human plasmas</u></b></p> <p style="text-align: center;">Instrument: STAR</p> <p style="text-align: center;">N: 22            Mean CT : 30,4 Sec.            SD: 1,4 Sec.            Range: 28,5 - 33,8 Sec.</p>	<p>N ≥ 20            28 to 35 Sec</p>						
<p><b>3. <u>Aspect</u></b></p> <p><input checked="" type="checkbox"/> Opalescent  <input checked="" type="checkbox"/> Presence of whitish to greyish siliceous sediments which disappear after agitation</p>	<p>Opalescent, possible presence of whitish to greyish siliceous sediments which disappear after agitation</p>						
<p><b>4. <u>Stability</u></b></p> <p style="text-align: center;"><b>Clotting time, on normal citrated human plasma</b></p> <p style="text-align: center;">Instrument: MC10</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 40%; text-align: center;">Stored</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1 week at 2-8°C</td> <td style="text-align: center;"><b>29,2 Sec</b></td> </tr> <tr> <td style="text-align: center;">1 week at RT (18-25°C)</td> <td style="text-align: center;"><b>28,7 Sec</b></td> </tr> </tbody> </table>		Stored	1 week at 2-8°C	<b>29,2 Sec</b>	1 week at RT (18-25°C)	<b>28,7 Sec</b>	<p>ΔCT stored/Fresh ≤ 3 Sec.</p>
	Stored						
1 week at 2-8°C	<b>29,2 Sec</b>						
1 week at RT (18-25°C)	<b>28,7 Sec</b>						

**Comments :**



**PASSED IN COMPLIANCE**

**Date :** 2017-01-27

**QC Manager :**

**S.LECOURT**