

## ANALYSIS CERTIFICATE

**CEPHEN 2.5 - #CK512K**

**Lot : F1701340**

**QC release: 2017-11-24**

**Expiration date : 2019-10-15**

Components	Volume (2.5mL)	Exp. (months)	Lot #	Exp. date
Cephen 2.5	6 vials	24	F172201340	2019-10-15

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Analytical data	Specifications						
<p><b>1. <u>Batch reproducibility</u> (various vials tested) on normal plasma</b></p> <p style="text-align: right;">N : 5            Mean CT : 31,7 Sec.            CV : 0,8 %</p>	<p>CV ≤ 3 %</p>						
<p><b>2. <u>aPTT on normal citrated human plasmas</u></b></p> <p style="text-align: right;">Instrument: STAR</p> <p style="text-align: right;">N: 30            Mean CT : 29,1 Sec.            SD: 2,4 Sec.            Range: 24,6 - 34,7 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 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: right;">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;">31,0 Sec</td> </tr> <tr> <td style="text-align: center;">1 week at RT (18-25°C)</td> <td style="text-align: center;">31,5 Sec</td> </tr> </tbody> </table>		Stored	1 week at 2-8°C	31,0 Sec	1 week at RT (18-25°C)	31,5 Sec	<p>ΔCT stored/Fresh ≤ 3 Sec.</p>
	Stored						
1 week at 2-8°C	31,0 Sec						
1 week at RT (18-25°C)	31,5 Sec						

**Comments :**



**PASSED IN COMPLIANCE**

**Date :** 2017-11-24

**QC Manager :**

**S.LECOURT**