**HYPHEN *BioMed***
ZAC Neuville Unicersité - 155 rue d'Eragny
95000 Neuville sur Oise (France)
Tel: 33.1.34.40.65.10 - Fax: 33.1.34.48.72.36

# ANALYSIS CERTIFICATE

**BIOPHEN PROTEIN C 5 - #221205** **Lot : F1700804**

**QC release: 2017-08-30** **Expiration date : 2020-01-13**

| Components | Volume | Exp. (months) | Lot # | Exp. date |
|---|---|---|---|---|
| **R1** : PROTAC® 0.80 IU | 4 vials | 30 | F171200804 | 2020-01-19 |
| **R2** : SaPC-21 - 4 mg | 4 vials | 30 | F171200804 | 2020-01-13 |

**HYPHEN *BioMed***
ZAC Neuville Unicersité - 155 rue d'Eragny
95000 Neuville sur Oise (France)
Tel: 33.1.34.40.65.10 - Fax: 33.1.34.48.72.36

# ANALYSIS CERTIFICATE

**BIOPHEN PROTEIN C 5 - #221205** **Lot : F1700804**

**QC release: 2017-08-30** **Expiration date : 2020-01-13**

| Analytical data | Specifications |
|---|---|
| **1. SaPC-21 substrate** | |
| **a.** Blank value (N=10) Mean (A405): **0,167** | A405 ≤ 0.30 |
| **b.** Stability of substrate blank (A405) | |
| Time / Fresh / 7 days<br>2-8°C / 0,149 / 0,151<br>R.T. / / 0,150 | **A405:**<br>7 days 2-8° C ≤ 0.30<br>7 days R.T. ≤ 0.30 |
| **c.** Reproducibility (100% APC) (manual method) | |
| N= **15** Mean (A405): **1,203** | A405 ≥ 0,80 |
| CV(DO): **1,15 %** | ≤ 2 % |
| **d.** Substrate aspect | |
| ☒ Clear ☒ Transparent ☒ Slightly yellow | Clear, Transparent Slightly yellow |

| | |
|---|---|
| **2. Protac® : Activated Protein C Activator** | |
| **a.** Reproducibility (100% PC) (manual method) | |
| N= **15** Mean (A405): **1,175** | A405 ≥ 0,80 |
| CV(DO): **1,39 %** | ≤ 2 % |
| **b.** Protac® aspect | |
| ☒ Clear ☒ Transparent | Clear, Transparent |

**HYPHEN *BioMed***
ZAC Neuville Université - 155 rue d'Eragny
95000 Neuville sur Oise (France)
Tel: 33.1.34.40.65.10 - Fax: 33.1.34.48.72.36

# ANALYSIS CERTIFICATE

**BIOPHEN PROTEIN C 5 - #221205** **Lot : F1700804**

**QC release: 2017-08-30** **Expiration date : 2020-01-13**

| Analytical data | Specifications |
|---|---|

## 3. Validation of PC method

**a.** Calibration curve (manual)

| %PC | | A405 |
|---|---|---|
| 0 | | 0,005 |
| C/4 | 25 | 0,315 |
| C/2 | 50 | 0,599 |
| C | 100 | 1,202 |

**100% PC:**
A405 ≥ 0,80

**0% PC:**
A405 ≤ 0.10

**b.** Linearity **Method : Water bath (manual)**

$R^2$ = **0,9997** $R^2 \geq 0.98$

**c.** Detection threshold **Method : STAR**

| | | | |
|---|---|---|---|
| (0%PC) | Mean (A405): | **0,001** | ≤ 0.10 |
| | SD: | **0,001** | |
| | Mean (A405) + 3 SD: | **0,004** | |
| | % PC: | **<5** | ≤ 5% |

**d.** Accuracy

| Control | TV* % PC | MV* % PC | |
|---|---|---|---|
| Normal Control | 89 | 92 | MV = TV ± 5% |
| Abnormal Control | 38 | 36 | MV = TV ± 8% |

*** TV= Target Value - MV= Measured Value**

**e.** Stability of calibration curve

| % PC | 0 | 26 | 52 | 104 | |
|---|---|---|---|---|---|
| Fresh | 0,001 | 0,126 | 0,251 | 0,509 | **Δ A405** (7 days) |
| 7 days at 2-8°C | 0,002 | 0,127 | 0,249 | 0,507 | ≤ 0.10 |
| 7 days at RT (18-25°C) | 0,002 | 0,122 | 0,249 | 0,505 | |

**HYPHEN *BioMed***
ZAC Neuville Université - 155 rue d'Eragny
95000 Neuville sur Oise (France)
Tel: 33.1.34.40.65.10 - Fax: 33.1.34.48.72.36

# ANALYSIS CERTIFICATE

**BIOPHEN PROTEIN C 5 - #221205** **Lot : F1700804**

**QC release: 2017-08-30** **Expiration date : 2020-01-13**

| Analytical data | Specifications |
|---|---|
| **f.** Automated method **Method :** STAR | |

| % PC | 0 | 25 | 50 | 100 |
|---|---|---|---|---|
| A405 | 0,001 | 0,122 | 0,241 | 0,494 |

$R^2$ = 1,000 — $R^2 \geq 0.98$

| Control | TV* % PC | MV* % PC | |
|---|---|---|---|
| Normal Control | 89 | 93 | MV = TV ± 5% |
| Abnormal Control | 38 | 38 | MV = TV ± 8% |

* TV= Target Value - MV= Measured Value

Comments :

[X] **PASSED IN COMPLIANCE**

**Date : 2017-08-30** **QC Manager : S. LECOURT**