

ANALYSIS CERTIFICATE

BIOPHEN PLASMA CALIBRATOR - #222101

Lot : 53701-1

QC Release : 16/11/2015

Expiration date : 2018-03

| Components | Volume | Exp. (months) | Lot # | Exp. date |
|-------------------|----------|------------------|---------|--------------|
| Plasma Calibrator | 12 vials | 30 | 53701-1 | 2018-03 |

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| Analytical data | | | | Specifications |
|--------------------------------------|--------|-----------|-----|----------------|
| 1. Within lot reproducibility | | | | |
| N= 55 | PT = | 14,3 Sec. | CV: | 0,7 % |
| N= 55 | APTT = | 31,9 Sec. | CV: | 1,2 % |
| | | | | CV ≤ 2% |
| | | | | CV ≤ 2% |

| 2. Value Assignment | | | | [C] |
|----------------------------|----------|----------|------|---------|
| Parameters | N series | [C] | SD | |
| Factor VII+X (%) | 6 | 110% | 3,08 | > 85% |
| ATIII (%) | 12 | 100% | 2,74 | > 85% |
| α2-Antiplasmin (%) | 6 | 106% | 2,34 | > 85% |
| Protein C chromogenic (%) | 8 | 104% | 1,58 | > 85% |
| Protein C clotting (%) | 7 | 86% | 3,09 | > 70% |
| Protein S clotting (%) | 6 | 90% | 2,34 | > 50% |
| Protein S free (Eihsa) (%) | 3 | 92% | 3,61 | > 70% |
| Factor VIII:C (%) | 11 | 100% | 5,19 | > 60% |
| Prothrombin (%) | 9 | 108% | 3,54 | > 80% |
| Factor V (%) | 7 | 110% | 2,48 | > 80% |
| Factor VII (%) | 11 | 114% | 4,67 | > 80% |
| Factor IX (%) | 9 | 100% | 5,49 | > 60% |
| Factor X (%) | 9 | 102% | 3,55 | > 80% |
| Factor XI (%) | 7 | 106% | 5,72 | > 70% |
| Factor XII (%) | 6 | 121% | 3,56 | > 70% |
| Plasminogen (%) | 13 | 104% | 4,16 | > 80% |
| Fibrinogen (g/L) | 8 | 3,22 g/L | 0,06 | > 2 g/L |
| vWF:Ag (%) | 6 | 102 | 1,8 | > 60% |
| DVVtest/confirm ratio | 4 | 0,94 | 0,05 | ≤ 1.20 |

| 3. Aspect | | |
|-------------------------------------|------------------------------|------------------------------|
| <input checked="" type="checkbox"/> | Slightly opalescent to clear | Slightly opalescent to clear |
| <input checked="" type="checkbox"/> | No coagulum | No coagulum |
| <input checked="" type="checkbox"/> | Stable | Stable solution |

| 4. Stability of reconstituted reagents | | | | | PT | APTT |
|--|-------------|-------|--------|-------|--------------|--------------|
| | PT | | APTT | | 8h at RT | 8h at RT |
| | sec | Δ sec | sec | Δ sec | 24h at 2-8°C | 24h at 2-8°C |
| Fresh | 13,9 | NA | 31,4 | NA | Δ CT ≤ 1sec | Δ CT ≤ 3sec |
| 24h / 2-8°C | 13,9 | 0 | 32,4 | 1,0 | | |
| 8h / RT | 13,8 | 0,1 | 31,0 | 0,4 | | |
| | FVIII:C (%) | | FV (%) | | VIII:C or V: | |
| | % | Δ % | % | Δ % | 4h at RT | 8h at 2-8°C |
| Fresh | 107 | NA | 117 | NA | Δ[C] ≤ 10% | |
| 8h / 2-8°C | 99 | 8 | 117 | 0 | | |
| 4h /RT | 105 | 2 | 112 | 5 | | |

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QC Release : 16/11/2015

Expiration date : 2018-03

| Analytical data | | | | | | | | Specifications |
|---|--|-----------|----------------|---------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|----------------|
| 5. Calibration, Linearity and Accuracy : | | | | | | | | |
| Parameters | Reagent used | Equipment | R ² | Normal control Acceptance Range | Normal Control Measured Value (*) | Abnormal control Acceptance Range | Abnormal Control Measured Value (*) | |
| Factor VII+X (%) | HEMOCLOT VII+X # CK051K / CK051L | STAR | 0,999 | [75 - 95] | 88 | [29 - 39] | 36 | |
| ATIII (%) | BIOPHEN Antithrombin 5 # 221105 | STAR | 0,998 | [76 - 96] | 91 | [29 - 39] | 37 | |
| α2-Antiplasmin (%) | BIOPHEN® α 2-Antiplasmin (LRT) # 220502 | CS5100 | 1,00 | [74 - 111] | 87 | [32 - 39] | 35 | |
| Protein C chromogenic (%) | BIOPHEN Protein C 5 # 221205 | STAR | 1,00 | [73 - 93] | 87 | [32 - 44] | 43 | |
| Protein C clotting (%) | HEMOCLOT Protein C # CK031K | STAR | 0,99 | [58 - 78] | 64 | [26 - 40] | 32 | |
| Protein S clotting (%) | HEMOCLOT Protein S # CK041K | STAR | 1,00 | [63 - 85] | 78 | [26 - 38] | 36 | |
| Protein S free (Elisa) (%) | ZYMUTEST FREE PROTEIN S # RK015A | Manuel | NA | [73 - 99] | 84 | [28 - 42] | 36 | |
| Factor VIII:C (%) | Factor VIII:C Deficient Plasma # DP040A - DP040K | STAR | 0,99 | [84 - 104] | 100 | [31 - 43] | 36 | |
| Prothrombin (%) | Prothrombin Deficient Plasma #DP010A - DP010K | STAR | 0,99 | [71 - 91] | 83 | [31 - 41] | 35 | |
| Factor V (%) | Factor V Deficient Plasma # DP020A - DP020K | STAR | 0,99 | [67 - 87] | 83 | [30 - 40] | 37 | |
| Factor VII (%) | Factor VII Deficient Plasma # DP030A - DP030K | STAR | 0,99 | [78 - 98] | 95 | [30 - 40] | 36 | |
| Factor IX (%) | Factor IX Deficient Plasma # DP050A - DP050K | STAR | 1,00 | [71 - 91] | 82 | [31 - 41] | 35 | |
| Factor X (%) | Factor X Deficient Plasma # DP060A - DP060K | STAR | 0,99 | [72 - 92] | 78 | [30 - 40] | 36 | |
| Factor XI (%) | Factor XI Deficient Plasma # DP070A - DP070K | STAR | 1,00 | [63 - 85] | 79 | [26 - 38] | 35 | |
| Factor XII (%) | Factor XII Deficient Plasma # DP080A - DP080K | STAR | 0,99 | [87 - 117] | 108 | [30 - 46] | 36 | |
| Plasminogen (%) | BIOPHEN® Plasminogen # 221502 | STAR | 1,00 | [80 - 100] | 94 | [34 - 46] | 38 | |
| Fibrinogen (µ/L) | Fibrinphen 5 # CK575 | STAR | 0,998 | [2,15 - 2,63] | 2,55 | [1,40 - 1,71] | 1,61 | |
| vWF:Ag (%) | LIAPHEN vWF:Ag #120206 | CS5100 | 1,00 | [77 - 105] | 91 | [38 - 56] | 47 | |

R² > 0.98
 MV* within the acceptance range

| | | |
|---|--|--|
| Comments : New CoA regarding availability of new parameter: vWF : Antigen | |  PASSED IN COMPLIANCE |
|---|--|--|

Date : 28/01/2017

QC Manager : 
 Marie PEYRAFITTE
 Resp. Validation

**BIOPHEN PLASMA CALIBRATOR**Normal Human Plasma for the calibration of some coagulation factors / *Plasma humain normal pour l'étalonnage de certains tests de coagulation***REF** 222101For in vitro diagnostic use only / *Pour diagnostic in vitro exclusivement***LOT**

53701-1



2018-03

| Parameters / Paramètres | Reagents / Réactifs | [C] % or Ratio |
|--|--|----------------|
| Factor VII+X (%) / <i>Facteur VII+X (%)</i> | HEMOCLOT VII+X | 110 % |
| AT III (Activity or Antigen) (%) / <i>AT III (Activité ou Antigène) (%)</i> | BIOPHEN Antithrombin 2.5 / BIOPHEN Antithrombin 5 / BIOPHEN AT anti-(h)-Xa LRT LIAPHEN AT | 100 % |
| $\alpha 2$ - Antiplasmin (%) / <i>$\alpha 2$ - Antiplasmine (%)</i> | BIOPHEN $\alpha 2$ -Antiplasmin (LRT) | 106 % |
| Protein C (Chromogenic) (%) / <i>Protéine C (Chromogène) (%)</i> | BIOPHEN Protein C 2.5 / BIOPHEN Protein C 5 / BIOPHEN Protein C (LRT) | 104 % |
| Protein C (Clotting) (%) / <i>Protéine C (Coagulante) (%)</i> | HEMOCLOT Protein C | 86 % |
| Protein S (Clotting) (%) / <i>Protéine S (Coagulante) (%)</i> | HEMOCLOT Protein S | 90 % |
| Free Protein S (Elisa) (%) / <i>Protéine S libre (Elisa) (%)</i> | ZYMUTEST FREE PROTEIN S | 92 % |
| Prothrombin (Clotting or Chromogenic) (%) / <i>Prothrombine (Coagulante ou Chromogène) (%)</i> | BIOPHEN Prothrombin / Prothrombin Deficient Plasma | 108 % |
| Factor V (Clotting) (%) / <i>Facteur V (Coagulante) (%)</i> | Factor V Deficient Plasma / HEMOCLOT Factor V REAGENT | 110 % |
| Factor VII (Clotting or Chromogenic) (%) / <i>Facteur VII (Coagulante ou Chromogène) (%)</i> | BIOPHEN VII / Factor VII Deficient Plasma / HEMOCLOT Factor VII REAGENT | 114 % |
| Factor VIII:C (Clotting or Chromogenic) (%) / <i>Facteur VIII:C (Coagulante ou Chromogène) (%)</i> | BIOPHEN FVIII:C / BIOPHEN FVIII:C (6) Factor VIII:C Deficient Plasma | 100 % |
| Factor IX (Clotting or Chromogenic) (%) / <i>Facteur IX (Coagulante ou Chromogène) (%)</i> | BIOPHEN Factor IX / BIOPHEN Factor IX (8) Factor IX Deficient Plasma | 100 % |
| Factor X (Clotting or Chromogenic) (%) / <i>Facteur X (Coagulante ou Chromogène) (%)</i> | BIOPHEN Factor X / Factor X Deficient Plasma | 102 % |
| Factor XI (Clotting) (%) / <i>Facteur XI (Coagulante) (%)</i> | Factor XI Deficient Plasma | 106 % |
| Factor XII (Clotting) (%) / <i>Facteur XII (Coagulante) (%)</i> | Factor XII Deficient Plasma | 121 % |
| Plasminogen (Chromogenic) (%) / <i>Plasminogène (Chromogène) (%)</i> | BIOPHEN Plasminogen / BIOPHEN Plasminogen (LRT) | 104 % |
| Fibrinogen (Activity or Antigen) (g/L) / <i>Fibrinogène (Activité ou Antigène) (g/L)</i> | Fibrphen 1 / Fibrphen 2 / Fibrphen 5 / LIAPHEN Fibrinogen | 3,22g/L |
| von Willebrand Factor (Antigen) (%) / <i>Facteur von Willebrand (Antigène) (%)</i> | LIAPHEN vWF:Ag | 102% |
| (DVVtest / DVVconfirm) / <i>(DVVtest / DVVconfirm)</i> | DWV / DWVt (ADI) | ≤ 1,20 |

Date of Approval/ *Date d'Approbation* : 28/04/2017Quality Control Manager / *Responsable Contrôle Qualité* :Marie PEYRAFITTE
Resp. Validation