BIOPHEN™ Normal Control Plasma

REF 223201-RUO

C1 12 x 1 mL

Normal Plasma for the quality control of coagulation assays.
FOR RESEARCH USE ONLY.
DO NOT USE IN DIAGNOSTIC PROCEDURES.

HYPHEN BioMed
www.hyphen-biomed.com
155, rue d'Eragny
95000 NEUVILLE SUR OISE
FRANCE
Tel. : +33 (0)1 34 40 65 10
Fax : +33 (0)1 34 48 72 36
info@hyphen-biomed.com

English, Last revision: 01-2018

INTENDED USE:

The BIOPHEN™ Normal Control Plasma kit is a set of normal citrated human plasma, lyophilized, intended for the quality control of some coagulation factors assays.
This kit is for research use only and must not be used for patient diagnosis or treatment.

SUMMARY AND EXPLANATION:

The following table shows the various parameters, which are measured using assays from HYPHEN BioMed or other manufacturers, and according to the package inserts:

Parameter	Method
PT/INR/% and aPTT	Activity
Fibrinogen (Fbg)	Activity / Antigen
Thrombin Time (TT)	Activity
Lupus Anticoagulant (LA)	Activity
α2 – Antiplasmin (α2-AP)	Activity
Antithrombin (AT)	Activity / Antigen
Prothrombin (FII)	Activity
Factor V (FV)	Activity
Factor VII (FVII)	Activity
Factor VII + X (FVII + X)	Activity
Factor VIII:C (FVIII)	Activity
Factor IX (FIX)	Activity
Factor X (FX)	Activity
Factor XI (FXI)	Activity
Factor XII (FXII)	Activity
Factor XIII (FXIII)	Activity
Plasminogen (Plg)	Activity
Protein C (PC)	Clotting activity
Protein C (PC)	Chromogenic activity
Protein S (PS)	Clotting activity
Free Protein S (Free PS)	Antigen
von Willebrand Factor Antigen (vWF: Ag)	Antigen
Act PC-r	Clotting Ratio (Qualitative)
ActPCr (% FVL)	Clotting (Quantitative)

The BIOPHEN™ Normal Control Plasma is tested for the absence of Lupus Anticoagulant. It can be used as a negative control for this investigation. This control plasma is also tested for the absence of Activated Protein C resistance (Act PC-r). When the aPTT is performed with or without Activated Protein C (APC) the ratio obtained (aPTT + APC/aPTT) is ≥ 2.00. When tested with Hemoclot Quanti VL kit, the expected value is <10% FVL.

REAGENTS:

C1 **Normal citrated human plasma,** lyophilized.
12 vials of 1mL.

The control concentrations may vary slightly from one batch to the next. For the assay, see the exact values provided on the flyer provided with the kit used.

WARNINGS AND PRECAUTIONS:

- Control plasma contains stabilizing agents.
- Each pouch of human plasma used for kit preparation was obtained from healthy donors. Each plasma used was screened for the presence of the HBs antigen, of anti-HIV1, anti-HIV2 and anti-HCV antibodies, using approved methods, and found to be negative. Nevertheless, no tests can totally exclude the presence of infectious agents. For this reason, every precaution required for the use of potentially infectious products should be taken when handling and disposing of plasma.
- Waste should be disposed of in accordance with applicable local regulations.
- Handle the reagents with care to avoid contamination during use. If possible, avoid reagent evaporation during use by limiting the liquid-air exchange surface. Evaporation reduces the reagent's stability in the analyzer.
- To ensure reagent stability, seal the vials after use with their respective caps, or close the plastic micro-containers into which the plasmas may have been transferred, depending on the protocol used.
- Aging studies, conducted over a 3-week period at 30 °C, show that the reagents can be shipped at room temperature over a short period of time, without degradation.
- It is recommended to homogenize each vial before use, in order to have a good reproducibility, all the time.
- For *in vitro* use.

REAGENT PREPARATION AND STABILITY:

The reagents are lyophilized under a vacuum in their vials. To avoid any product loss when opening the vial of lyophilized reagents, gently remove the freeze-drying stopper.

C1 Normal citrated human plasma

Reconstitute the contents of each vial with exactly **1 mL distilled water**, shake vigorously until fully dissolved.
Allow to stabilize for 30 min. at room temperature (18-25°C), shaking occasionally.
Homogenize prior to use.
Reagent stability after reconstitution, free from any contamination or evaporation, and stored in the original vial, is of:

- For AT, PC; VII-X, Plasminogen, FII, FVII, FIX, FX, FXI, FXII, FXIII, Fibrinogen, aPCr (%FVL), lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag, α2–AP and Thrombin Time:
  - **24 hours** at 2-8°C.
  - **8 hours** at room temperature (18-25°C).
  - Frozen at -20°C or less*
- For FVIII:C, FV and PS:
  - **8 hours** at 2-8°C.
  - **4 hours** at room temperature (18-25°C).
  - Frozen at -20°C or less*

*Thaw only once, as rapidly as possible at 37°C, adapting the incubation period to the volume of reagent. The stability of the thawed reagent should be checked under laboratory work conditions.

STORAGE CONDITIONS:

Unopened reagents should be stored at 2-8°C in their original packaging. Under these conditions, they can be used until the expiry date printed on the kit.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:

- Distilled water.

Materials:

- Calibrated pipettes.

TRACEABILITY:

The value assignment of the various parameters reported is related to the corresponding International Standards, when available, or against an internal reference.

PROPERTIES:

The BIOPHEN™ Normal Control Plasma is used for the quality control of some coagulation assays.
The control target values are determined from multi-reagent and multi-instrument tests.
The use of quality controls serves to validate method compliance, along with between-series assay homogeneity for a given batch of reagents.
Include the quality controls with each series, as per good laboratory practice, in order to validate the test.
If the controls fall outside of the acceptable range, the series of assays must be invalidated and the analyses repeated. Check all system parameters before repeating the series.
The results obtained for VII-X assay can slightly vary according to the thromboplastin reagent type and lot, and the instrument used. The target value and acceptance range for VII-X parameter must consequently be confirmed and adjusted, if necessary, for each new lot of control, in the laboratory working conditions.
PT and aPTT results must be checked and adjusted if necessary in the same way.

LIMITATIONS:

- Like all lyophilized plasmas, control plasmas are more or less turbid once resuspended. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit.
- Any plasma displaying a coagulum or showing signs of bacterial or fungal contamination must be rejected.
- If the controls are used under measurement conditions other than those validated by HYPHEN BioMed, the test results may vary. The laboratory is responsible for validating the use of these controls in its own analytical system.
- If necessary, let each vial 10 minutes at room temperature and shake before use in order to homogenize the content.

The results obtained should be for research use only and must not be used for patient diagnosis or treatment.

SYMBOLS:

Symbols used and signs listed in the ISO 15223-1 standard, see Symbol definitions document.

Changes compared to the previous version.