BIOPHEN™ Normal Control Plasma

REF 223201-RUO

C1 12 x 1 mL

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Normal Plasma for the quality control of coagulation assays.

FOR RESEARCH USE ONLY.
DO NOT USE IN DIAGNOSTIC PROCEDURES.

English, Last revision: 11-2021

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:

Technical:
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 C (PC)	Antigen
Protein S (PS)	Clotting activity
Free Protein S (Free PS)	Antigen
von Willebrand Factor Antigen (vWF: Ag)	Antigen
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 (CK065K) from HYPHEN BioMed, the expected value is <10% FVL.

REAGENTS:

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

Control plasma contains stabilizing agents.

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

WARNINGS AND PRECAUTIONS:

- Some reagents provided in these kits contain materials of human origin. Whenever human plasma is required for the preparation of these reagents, approved methods are used to test the plasma for the antibodies to HIV 1, HIV 2 and HCV, and for hepatitis B surface antigen, and results are found to be negative. However, no test method can offer complete assurance that infectious agents are absent. Therefore, users of reagents of these types must exercise extreme care in full compliance with safety precautions in the manipulation of these biological materials as if they were infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- Use only the reagents from the same batch of kits.
- Aging studies show that the reagents can be shipped at room temperature without degradation.
- This device of *in vitro* use is intended for professional use in the laboratory.

REAGENT PREPARATION:

Gently remove the freeze-drying stopper, to avoid any product loss when opening the vial.

C1 Reconstitute the contents of each vial with exactly **1 mL of distilled water.**
Shake vigorously until complete dissolution while avoiding formation of foam and load it directly on the analyzer following application guide instruction.
For manual method, allow to stabilize for 30 minutes at room temperature (18-25°C), homogenize before use.

This plasmatic reagent can be more or less turbid after reconstitution. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit. If necessary, let each vial stabilize 10 minutes at room temperature and shake before use.

STORAGE AND STABILITY:

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.

C1 Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, 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).
  - **2 months** at -20°C or less*
  - **Stability on board of the analyzer: see the specific application.**
- For FVIII:C, FV and PS:
  - **8 hours** at 2-8°C.
  - **4 hours** at room temperature (18-25°C).
  - **2 months** at -20°C or less*
  - **Stability on board of the analyzer: see the specific application.**

*Thaw only once, as rapidly as possible at 37°C and use immediately.

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.

QUALITY CONTROL:

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 acceptance 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:

- 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.
- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.

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.