BIOPHEN™ Normal Control Plasma

REF 223201

C1 12 x 1 mL

CE IVD

Normal Control Plasma for coagulation assay quality control.

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

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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.

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:

Assays	Reagents	Manufacturers	Reference
Antithrombin	BIOPHEN™ Antithrombin	HYPHEN BioMed	221102 221105
Protein C	BIOPHEN™ Protein C	HYPHEN BioMed	221202 221205
aPC resistance (FV Leiden)	HEMOCLOT™ VL Quanti	HYPHEN BioMed	CK065K
Lupus Anticoagulant	DVVtest® DVVconfirm®	Biomedica Diagnostics	810 815 / 815L

DVVtest, DVVconfirm are registered trade marks from Biomedica Diagnostics Inc.
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.

Control plasma contains stabilizing agents.

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.

The following table shows the usual ranges expected for the BIOPHEN™ Normal Control Plasma.

Assays	Reagents	Acceptance range
Antithrombin	BIOPHEN™ Antithrombin	> 80%
Protein C	BIOPHEN™ Protein C	> 80%
Lupus Anticoagulant	DVVtest/DVVconfirm	≤ 1.2
Act PC-r	Ratio APTT ± APC	≥ 2.00
ActPCr (% FVL)	HEMOCLOT™ Quanti VL	<10%

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.
- 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.
- This device of *in vitro* diagnostic 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:

- **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.**

*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 acceptable range, the series of assays must be invalidated and the analyses repeated. Check all system parameters before repeating the series.

PERFORMANCES:

The following values, obtained for one lot of BIOPHEN™ Normal Control Plasma, are provided as an example only.

Parameter	Concentration	Acceptance range	N	CV (%)
Antithrombin	99%	89-109	9	1.4
Protein C	102%	92-112	9	1.8
DVVtest/DVVconfirm ratio	1.12	≤ 1.2	9	/
Act PC-r ratio	2.3	≥ 2.0	2	/
ActPCr (% FVL)	<5%	<10%	9	1.9

For each parameter, the concentration and acceptance range may present variations from lot to lot, but it is exactly measured for each lot and reported on the flyer provided within the kit.

When the BIOPHEN™ Normal Control Plasma is used as quality control plasma for the assay of coagulation factors, the values obtained must be within the acceptance ranges reported for the lot used, in order to validate the test series. Should the value be out of these ranges, the results for the corresponding series must be considered as invalid. It is then recommended to rerun the series and to check all the assay parameters.

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 plasma displaying a coagulum or showing signs of bacterial or fungal contamination must be rejected.
- If necessary, let each vial stand 10 minutes at room temperature and shake before use in order to homogenize the contents.

SYMBOLS:

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

Changes compared to the previous version.