

**BIOPHEN  
NORMAL CONTROL PLASMA  
Ref A223201**

Normal Control Plasma for coagulation assay quality control

For in vitro diagnostic use only



**Manufactured By: HYPHEN BioMed**

Last revision: 30/05/2008

**INTENDED USE:**

BIOPHEN Normal Control Plasma is a set of 12 vials of normal citrated human plasma for the quality control of some coagulation factors. The following table shows the various parameters, which are measured using assays from HYPHEN BioMed or from other manufacturers, and according to the package inserts:

Assays	Reagents	Manufacturers	Reference
<b>ATIII</b>	Biophen ATIII	Hyphen BioMed	A221102 A221105
<b>Protein C</b>	Biophen Protein C	Hyphen BioMed	A221202 A221205
<b>aPC resistance (FV Leiden)</b>	Hemoclot FVL Quanti	Hyphen BioMed	ACK065K
<b>Lupus Anticoagulant</b>	DVVtest® DVVconfirm®	American Diagnostica	810 815 / 815L

DVVtest, DVVconfirm are registered trade marks from American Diagnostica Inc.

The BIOPHEN Normal Control Plasma is tested for the absence of Lupus Anticoagulant and 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  $\geq 2.00$ .

**REAGENTS SUPPLIED:**

12 vials of 1 ml of normal citrated human plasma, lyophilised.

**Note:**

- BIOPHEN Normal Control Plasma contains an antibiotic as preservative.
- Each donor unit used for the preparation of BIOPHEN Normal Control Plasma is a human plasma, which has been tested with registered methods for the presence of Hepatitis B Surface Antigen, Hepatitis C Antibodies (HVC) and antibodies to HIV 1 and 2 and was found negative. However, no test can completely exclude the presence of infectious agents. Any product of human origin, and more especially plasma, must be considered as being potentially infectious and must be handled with all the required cautions for this kind of material.

**STORAGE CONDITIONS:**

Unopened reagents, must be stored at 2–8 °C, in their original packaging box. They are then stable until the expiration date printed on the label.

**Note:** The stability studies at 30°C show that the reagents can be shipped at room temperature without damage.

**PREPARATION AND STABILITY OF REAGENTS:**

Reconstitute each vial with exactly 1 mL of distilled water. Shake thoroughly until complete dissolution of the content (vortex). Incubate at room temperature (18-25°C) for 30 min, while shaking the vial from time to time.

Homogenise the content before each use.

Stability of Normal control plasma, kept in its original vial:

- 8 hours at room temperature.
- 24 hours at 2-8°C.
- Do not freeze.

**Cautions:**

- In order to improve stability, reagents must be closed with their original screw caps following each use.
- Reagents must be handled with care, in order to avoid any contamination during use.

- It is recommended to homogenize each vial before use, in order to have a good reproducibility, all the time.

**APPLICATIONS:**

BIOPHEN Normal Control Plasma can be used as a normal control plasma for some coagulation assays. For each lot, the concentrations and acceptance ranges are reported for each parameter tested on the flyer provided within the kit.

The various parameters reported (Antithrombin III, Protein C) are accurately determined by reference to the corresponding NIBSC (National Institute for Biological Standards and Controls, UK) International Standards, when available.

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

Assays	Reagents	Acceptance range
<b>ATIII</b>	Biophen ATIII	> 80%
<b>Protein C</b>	Biophen Protein C	> 80%
<b>Lupus Anticoagulant</b>	DVVtest/DVVconfirm	$\leq 1.2$
<b>Act PC-r</b>	Ratio APTT $\pm$ APC	$\geq 2.00$
<b>ActPCr (% FVL)</b>	Hemoclot Quanti VL	<10%

**PERFORMANCE CHARACTERISTICS:**

The following values, obtained for a BIOPHEN Normal Control Plasma, are provided as an example only.

Parameter	[C]	Acceptance range	N	CV (%)
ATIII	99%	89-109	9	1.4
Protein C	102%	92-112	9	1.8
DVVtest/DVVconfirm ratio	1.12	$\leq 1.2$	9	/
Act PC-r ratio	2.3	$\geq 2.0$	2	/
<b>ActPCr (% FVL)</b>	<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.

**CAUTIONS:**

- Like all lyophilised plasmas, the plasmas from the BIOPHEN Normal Control Plasma are more or less cloudy after reconstitution. This is due essentially to the lipids that, after lyophilisation, become less soluble and can form a light deposit.
- If necessary, let each vial 10 minutes at room temperature and shake gently before use in order to homogenise the content.
- Reagents must be handled with care, in order to avoid any contamination or activation during use. Any plasma containing a coagulum or contamination must be rejected.

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