

**BIOPHEN**
NORMALPLASMA 5
Ref 223605

Normal human citrated plasma for laboratory studies

In vitro diagnostic use only

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ENGLISH**INTENDED USE:**

BIOPHEN NormalPlasma 5 is a set of 8 vials of 5 mL of lyophilized normal citrated human plasma proposed for laboratory studies.

It can be used for diluting plasmas for the diagnosis of Lupus Anticoagulant. It is also useful as a non-titrated human plasma for the quality control of most of the haemostasis assays.

The BIOPHEN NormalPlasma 5 is tested for the absence of Lupus Anticoagulant and can be used as a negative control for this investigation.

REAGENTS SUPPLIED:

8 vials of 5 mL of normal citrated human plasma, lyophilised.

Note:

1. BIOPHEN NormalPlasma 5 contains an antibiotic as preservative (ciprofloxacin)
2. Each donor unit used for the preparation of control plasmas (BIOPHEN NormalPlasma 5) 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. Kept in their original packaging 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:**Preparation:**

- Reconstitute each vial with exactly 5 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 after reconstitution:

- 24 hours at 2-8°C.
- 8 hours at room temperature.

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 NormalPlasma 5 can be used as a non-titrated quality control human citrated plasma for coagulation assays.

BIOPHEN NormalPlasma 5 is also proposed as a dilution plasma for the assay of Lupus Anticoagulant (LA) with usual laboratory methods (See section "CAUTIONS" for the reagent).

SPECIFICATIONS:

BIOPHEN NormalPlasma 5 has a Prothrombin Time (PT) and an Activated Partial Thromboplastin Time (APTT) within the normal range. It is also tested for being normal for fibrinogen concentration and for the absence of Lupus Anticoagulant with the DVVtest (Diluted Russel Viper Venom Test). Factor VIII:C concentration is between 50 and 100%.

PERFORMANCE:

- This plasma is controlled for each lot for compliance with the here above specifications.
- PT, APTT and Fibrinogen concentrations may vary from lot to lot, but they are always within the normal range. Results may also present variations according to the reagent used.
- This BIOPHEN NormalPlasma 5 is a non-titrated normal citrated human plasma, but it is not a calibrator for haemostasis parameters and it must not be used for this latter application.

CAUTIONS:

- Like all lyophilised plasmas, the plasmas from the BIOPHEN NormalPlasma 5 kit are more or less cloudy following reconstitution. This is due essentially to plasma lipids that, after lyophilisation, become less soluble and can form a light deposit.
- If necessary, let each vial for 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 a contamination must be rejected.
- BIOPHEN NormalPlasma 5 can be applied in many laboratory techniques. Each lot must be qualified for its compliance with the method used. Especially, when this normal plasma is used as diluent for testing lupus anticoagulant, each lot must be validated with the specific laboratory method