



BIOPHEN™ NormalPlasma 2

REF 223602

R1 10 x 2 mL

Normal human citrated plasma for laboratory studies

English, Last revision: 11-2017

INTENDED USE:

BIOPHEN™ NormalPlasma 2 kit is a set of lyophilized normal citrated human plasma proposed for laboratory studies.

BIOPHEN™ NormalPlasma 2 can be used for diluting plasmas for the assay of Lupus Anticoagulant. It is also useful as a non-titrated human plasma for the quality control of most of the assays on plasma.

BIOPHEN™ NormalPlasma 2 is tested for the absence of Lupus Anticoagulant and can be used as a negative control for this investigation.

SUMMARY AND EXPLANATION:

BIOPHEN™ NormalPlasma 2 kit can be used as a non-titrated quality control (human citrated plasma) for coagulation assays.

BIOPHEN™ NormalPlasma 2 is also proposed as a dilution plasma for the assay of Lupus Anticoagulant (LA) with usual laboratory methods (See section "LIMITATIONS" for the reagent).

REAGENTS:

R1 Normal citrated human plasma, lyophilized
10 vials of 2 mL.

WARNINGS AND PRECAUTIONS:

- Plasmas contain stabilizing agents.
- Biological products must be handled with all necessary precautions and considered as being potentially infectious.
- The human plasma used to prepare the plasma pool has been tested by recorded methods and is certified free of HIV antibodies, Hbs Antigen and HCV antibodies.
- 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 show that the reagents can be shipped at room temperature over a short period of time, without degradation.
- For *in vitro* diagnostic use.

REAGENT PREPARATION AND STABILITY:

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

R1 Reagent 1: Normal citrated human plasma

Reconstitute the contents of each vial with exactly 2 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:

- 24 hours at 2-8°C.
- 8 hours at room temperature (18-25°C).
- Do not freeze.

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:

This BIOPHEN™ NormalPlasma 2 is a non-titrated normal citrated human plasma, but it is not a calibrator for plasmatic parameters and it must not be used for this latter application.

PROPERTIES:

BIOPHEN™ NormalPlasma 2 has a Prothrombin Time (PT) and an Activated Partial Thromboplastin Time (APTT) within the usual range. It is also tested for being within the usual range 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%.

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 usual range. Results may also present variations according to the reagent used.

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.
- BIOPHEN™ NormalPlasma 2 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 for compliance with the specific laboratory method.

SYMBOLS:

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