EASYPLASMA™ Control Set

REF 225601-RUO

C1 6 x 1 mL, C2 6 x 1 mL

Normal and Abnormal Control Plasmas for the quality control of coagulation assays.

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

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INTENDED USE:

The EASYPLASMA™ Control Set is a set of normal and abnormal citrated human plasmas, 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	Clotting
Fibrinogen (Fbg)	Clotting
Thrombin Time (TT)	Clotting

REAGENTS:

C1 **Normal Control Plasma:** Normal citrated human plasma, lyophilized.
C2 **Abnormal Control Plasma:** Abnormal citrated human plasma, lyophilized.

Control Plasmas contain 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.

C1 C2 6 vials of 1mL.

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 C2 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 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 C2 Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- For Fibrinogen, PT/INR/%, Thrombin Time and aPTT:
  - **24 hours** at 2-8°C.
  - **8 hours** at room temperature (18-25°C).
  - **2 months** frozen 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 Fibrinogen is related to the corresponding International Standard. For other parameters, frozen normal plasma pool is used as reference.

QUALITY CONTROL:

The EASYPLASMA™ Control Set 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.

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.
- For parameters other than Fibrinogen, the values are determined against normal frozen plasma pool, and should be verified and adjusted as required against reference normal clotting time in the exact laboratory working conditions.

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.