GFC Control Plasmas

REF SC104K

C1 C2 C3 2 x 1 mL

Human plasmas for the quality control of the kit GFC-Test

FOR RESEARCH USE ONLY.

DO NOT USE IN DIAGNOSTIC PROCEDURES.

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INTENDED USE:

The GFC Control Plasmas kit is a set of control plasmas lyophilized intended for the quality control of the kit GFC-Test in plasma.
This kit is for research use only and should not be used for patient diagnosis or treatment.

SUMMARY AND EXPLANATION:

Fibrinolysis is the mechanism leading to fibrin clot dissolution in order to restore vessel patency or to dissolve a clot following the healing of a vessel injury.
It involves various proteins, that act either as inhibitors, delaying clot dissolution, (PAI-1, Alpha-2-antiplasmin, TAFI, HRGP…), or as activators that enable fibrin polymer breakdown (tPA, uPA, plasminogen). Plasminogen plays the central role in that process: after its activation into plasmin by either tissue plasminogen activator (tPA) or urokinase (uPA), it cleaves fibrin polymer.
Hyperfibrinolysis has been associated with mild to severe bleeding tendency, especially during surgery and invasive procedures. It is associated with increased morbidity and mortality.
Hypofibrinolysis is a risk factor for thrombosis and may become a predictive marker of venous thromboembolism and arterial thrombosis.

REAGENTS:

C1 **Hyperfibrinolysis Control :** Citrated human plasma spiked with tPA, lyophilized form.
2 vials of 1 mL.
C2 **Normal GFC Control :** Normal citrated human plasma, lyophilized form.
2 vials of 1 mL.
C3 **Hypofibrinolysis Control:** Citrated human plasma spiked with aprotinin, lyophilized form.
2 vials of 1 mL.

Control Plasmas contain stabilizing agents.

The control lysis time may vary slightly from one batch to another. For the assay, see the exact values indicated on the flyer provided with the kit used.

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 C3 Reconstitute the contents of each vial with exactly **1 mL of distilled water.**
Shake vigorously until complete dissolution while avoiding formation of foam and allow to stabilize for 10 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 C3 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** frozen at -20°C or less*

*Thaw only once, as rapidly as possible at 37°C and use immediately.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:

- Distilled water.

Product Name	Reference
GFC-Test	CK093K

Materials:

- Calibrated pipettes.

QUALITY CONTROL:

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.

The results obtained should be for research use only and must not be used for patient diagnosis or treatment.

REFERENCES:

1. Pepperell D. *et al.* Clinical Application of Fibrinolytic Assays in Fibrinolysis and Thrombolysis, InTech Publishers. 2014.
2. Lisman T. *et al.* Reduced plasma fibrinolytic potential is a risk factor for venous thrombosis. Blood. 2005 .
3. Rijken DC. *et al.* Development of a new test for the global fibrinolytic capacity in whole blood. J Thromb Haemost. 2008.
4. Zouaoui Boudjeltia K. *et al.* A new device for measurement of fibrin clot lysis: application to the Euglobulin Clot Lysis Time. BMC Biotechnology. 2002.

SYMBOLS:

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

Changes compared to the previous version.