DDimer Control Plasma

REF SC101K, C1 6 x 1 mL
REF SC102K, C2 6 x 1 mL
REF SC103K, C3 6 x 1 mL

Human plasmas for the quality control of D-Dimer assays.
FOR RESEARCH USE ONLY.
DO NOT USE IN DIAGNOSTIC PROCEDURES.

HYPHEN BioMed
www.hyphen-biomed.com
155, rue d'Eragny
95000 NEUVILLE SUR OISE
FRANCE
Tel. : +33 (0)1 34 40 65 10
Fax : +33 (0)1 34 48 72 36
info@hyphen-biomed.com

English, Last revision: 06-2020

INTENDED USE:

The DDimer Control Plasma kits consist of lyophilized human plasmas, spiked with D-Dimer at various concentration, for the quality control of D-Dimer assays.
This kit is for research use only and must not be used for patient diagnosis or treatment.

SUMMARY AND EXPLANATION:

Technical:
This control is proposed for the quality control of D-Dimer assays on plasma.

REAGENTS:

C1 High Positive DDimer Control Plasma
REF SC101K : Lyophilized human plasma containing a D-Dimer concentration of approximately 2 µg/mL.

C2 Negative DDimer Control Plasma
REF SC102K : Lyophilized human plasma containing a D-Dimer concentration below 0.50 µg/mL.

C3 DDimer Control Plasma Low
REF SC103K : Lyophilized human plasma containing a D-Dimer concentration of approximately 0.80 µg/mL.

6 vials of 1 mL.

Controls contain stabilizing agents.

The control concentrations may vary slightly from one batch to another. For the assay, see the exact indicative 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.
- 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 until complete dissolution while avoiding formation of foam and allow to stabilize for 15 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 stabilize 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:

- **48 hours** at 2-8°C.
- **24 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.

Materials:
- Calibrated pipettes.

TRACEABILITY:

The D-Dimer indicative concentration is indicated on the flyer.

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 acceptable range validated by the final user, 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.

SYMBOLS:

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

Changes compared to the previous version.