LA Control Plasma Weak

Ref SC082K-RUO (6 x 0.5 mL)

Weak positive human plasma for the quality control of Lupus Anticoagulant clotting assays.

FOR RESEARCH USE ONLY.

NOT FOR USE IN DIAGNOSTIC PROCEDURES.

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INTENDED USE:

LA Control Plasma Weak Kit contains a set of lyophilized quality control plasmas, weak positive, for use in Lupus Anticoagulant in vitro clotting assays. This kit is optimized for being used with the **HEMOCLOT™ LA-S and HEMOCLOT™ LA-C** assays **(#CK090K-RUO/CK091K-RUO).**

This kit is for research use only and should not be used for patient diagnosis or treatment.

REAGENTS:

The LA Control Plasma Weak kit contains 6 vials of 0.5 mL of weak positive human plasma for lupus anticoagulant.

C1: LA Control "Weak positive": indicative normalized ratio around 1.40.
Human plasma, lyophilized, 6 vials of 0.5 mL.

The clotting time for control is indicated for information only on the flyer provided in the kit. The clotting time for the controls may slightly vary from lot to lot and depending on the test system. For the assay, refer indicatively to the clotting time indicated on the flyer provided in the kit used.

CAUTIONS AND WARNINGS:

- Control plasmas contain stabilizers.
- Each human plasma unit is from healthy donors. Each plasma 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 then be handled with all the required cautions, as being potentially infectious.
- The disposal of waste materials must be carried out according to current local regulations.
- Reagents must be handled with care, in order to avoid any contamination during use. Take care to limit as much as possible any evaporation of the reagents during use, by limiting the liquid-air surface exchange. Evaporation reduces reagent stability on instrument board.
- In order to ensure stability, reagents must be closed with their original screw cap following each use, or stored closed in the micro plastic containers in which the control could be aliquoted (depending on the protocol and the instrument used).
- Stability studies for 3 weeks at 30°C show that the reagents can be shipped at room temperature for a short period without damage.
- Incubating the reconstituted vials at room temperature allows stabilizing the reagents, and obtaining a homogeneous reactivity.
- It is recommended to homogenize each vial before use, in order to have a good reproducibility, all the time.
- For *in vitro* use.

PREPARATION AND STABILITY OF REAGENTS:

Vials are closed under vacuum. Remove carefully the stopper, in order to avoid any loss of powder when opening the vials.

Controls:

Reconstitute each vial with exactly **0.5 mL** of distilled water, shake thoroughly for complete homogenization, let the reagent stabilize for 30 min at room temperature (18-25°C); while shaking the vial from time to time.

Homogenize before each use.

Stability of reconstituted reagent, provided that any contamination or evaporation is avoided, kept in its original vial is:

- **24 hours** at 2-8°C.
- **8 hours** at room temperature (18-25 °C).
- **7 days** frozen at -20°C or below*

*Thaw once as rapidly as possible at 37°C, adapt duration to the volume of reagent. The stability of the thawed reagent should be verified in the working conditions of the user laboratory.

STORAGE CONDITIONS:

Unopened reagents must be stored at 2-8°C, in their original packaging box. They are then usable until the expiration date printed on the kit.

TRACEABILITY:

Normal frozen plasma pool is used for the determination of normalized ratio.

CHARACTERISTICS:

The LA Control Plasma Weak is proposed for the quality control of lupus anticoagulant assays using **HEMOCLOT™ LA-S and HEMOCLOT™LA-C kit (#CK090K-RUO/CK091K-RUO)**.

It allows validating the homogeneous reactivity from run to run, when using a same lot of reagents. Quality controls must be included in each series, as per good laboratory practice, in order to validate generated results.

If control is out of the acceptance range, the test series must be invalidated, and the assay should be rerun. Check all the components of the test system, before repeating the assay.

If used with assays or instruments from other manufacturers, measured values can vary according to the assay reactivity and its standardization: each laboratory must then determine and validate the appropriateness of using this control and expected range in its specific assay conditions (reagent lot, instrument and protocol used).

LIMITATIONS:

- As all lyophilized plasmas, control plasmas are more or less cloudy after reconstitution. This is due essentially to lipids that, after lyophilization, become "less" soluble and can form a small deposit.
- Any plasma containing a coagulum or bacteriological or fungal contamination must be rejected.
- If the controls are used in other measurement conditions than those validated by HYPHEN BioMed, test results may vary. It is the responsibility of the laboratory to validate the use of these controls in its analytical system.

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

SYMBOLS:

Used symbols and signs listed in the ISO standard 15223-1.