LA CONTROL PLASMA

Ref SC081K (6 x 0.5 mL)

IVD

Positive human plasmas for the quality control of Lupus Anticoagulant clotting assays.

Not for Sale in the US

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: 10-2016

INTENDED USE:

LA Positive Control Plasma Kit is a set of lyophilized quality control plasmas, weak and high 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/CK091K).**

SUMMARY AND EXPLANATION:

"Lupus anticoagulant" is associated with numerous clinical states including eg lupus, thrombosis, foetal loss...and must usually be confirmed from multiple assays. These control plasmas are then proposed for the quality control of Lupus anticoagulant detection in plasma using in vitro clotting assays, especially **HEMOCLOT™ LA-S and HEMOCLOT™ LA-C** assays **(#CK090K/CK091K).**

REAGENTS:

The LA CONTROL PLASMA kit contains 12 vials of 0.5 mL of positive human plasma for lupus anticoagulant at two different levels (6 vials for each level).

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

C2: LA Control "High positive: indicative normalized ratio around 2.40.
Human plasma, lyophilized, 6 vials of 0.5 mL

The clotting time for each 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 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 diagnostic 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 reagent, provided that any contamination or evaporation is avoided, kept in its original vial or in a closed plastic microcentrifuge tube:

- **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 label.

TRACEABILITY:

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

CHARACTERISTICS:

The LA CONTROL PLASMA set is proposed for the quality control of lupus anticoagulant assays using HEMOCLOT™ LA-S and HEMOCLOT™LA-C kit (#CK090K/CK091K).

The mean normalized ratio by reference to a normal plasma pool is usually indicatively expected in the range 1.25-1.60 for control C1 (weak) and in the range 1.80-3.00 for control C2 (High) on STA-R® analyzers.

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 controls are 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 a contamination sign must be rejected.

REFERENCES:

1. SSC/ISTH 2009 Updated guidelines for Lupus anticoagulant detection
2. NCCLS/CLSI guideline Laboratory testing for the Lupus anticoagulant, approved guideline (H60-A)
3. GEHT and NCCLS/CLSI guidelines (H21-A5)
4. Rausch J, Tannenbaum M, Janoff AS. Distinguishing lupus anticoagulants from antifactor antibodies using hexagonal phase II phospholipids Thromb Haemost 1989; 62; 892-896.

SYMBOLS:

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

Changes compared to the previous version.