LA CONTROL PLASMA

REF SC081K

C1 C2 6 x 0.5 mL

IVD

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

HYPHEN BioMed

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English, Last revision: 09-2017

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 Plasma Weak:** indicative normalized ratio around 1.40.
Human plasma, lyophilized, 6 vials of 0.5 mL.

C2 **LA Control Plasma High:** 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 pouch of human plasma used for kit preparation was obtained from healthy donors. Each plasma used was screened for the presence of the HBs antigen, of anti-HIV1, anti-HIV2 and anti-HCV antibodies, using approved methods, and found to be negative. Nevertheless, no tests can totally exclude the presence of infectious agents. For this reason, every precaution required for the use of potentially infectious products should be take when handling and disposing of plasma.
- Waste should be disposed of in accordance with applicable local regulations.
- Handle the reagents with care to avoid contamination during use. If possible, avoid reagent evaporation during use by limiting the liquid-air exchange surface. Evaporation reduces the reagent's stability in the analyzer.
- To ensure reagent stability, seal the vials after use with their respective caps, or close the plastic micro-containers into which the plasmas may have been transferred, depending on the protocol used.
- Aging studies, conducted over a 3-week period at 30°C, show that the reagents can be shipped at room temperature over a short period of time, without degradation.
- 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:

The reagents are lyophilized under vacuum in their vials. To avoid any product loss when opening the vial of lyophilized reagents, gently remove the freeze-drying stopper.

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.
Reagent stability after reconstitution, free from any contamination or evaporation, and stored in the original vial, is of:

- **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 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.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:

- Distilled water.

Materials:

- Calibrated pipettes.

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:

- Like all lyophilized plasmas, control plasmas are more or less turbid once resuspended. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit.
- Any plasma displaying a coagulum or showing signs of bacterial or fungal contamination must be rejected.
- 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.

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:

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

Changes compared to the previous version.