COAGULATION CONTROLS

'In vitro' Analysis quality controls for haemostasis study in normal and pathological samples.

TEST PRINCIPLE

The evaluation of appropriate material in the analysis sequence, allows to verify the overall imprecision of the procedure adopted. The use of human plasma as a control material, ensures the commutability results obtained in the Quality Control process with similar samples activities incognita.
Coagulation controls can be used to monitor the Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and Fibrinogen.

REAGENTS

Human plasma, collected whit Sodium citrate, treat and liophilized.

PRESERVATION AND STABILITY

Preserve the product at 2-8°C, stable until expiration date on the package.
Once opened controls are stable for 8 hours at 2-8-°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Automatic Micropipette, normal laboratory equipment, distilled or deionizated water.

CONTROLS PREPARATION AND STORAGE

Open carefully the vial, trying to avoid loss of material, and with the enclosed pipette add exactly 1 ml of distilled water, for this is better employing an automatic pipette.
Close with attention and let the liophile recovers for 30 minutes, shake carefully trying to avoid foam formation.
Bring controls at 15-25°C before use.

PROCEDURE

Treat the reconstituted control was as a sample and perform the test following the analytical procedure provided for the reagent used.

EXPECTED VALUES

The reference ranges are defined taking into account the variability of preparation, recovery products and equipment, through statistical processing of data collected.
The value of each component is shown in the attached table.

PRECAUTIONS

- The blood of donors of biological substances used for products preparation, has been tested and found negative for HbsAg and antibodies anti-HIV and HCV.
- However no known test can offer complete assurance that products derived from human blood can not transmit hepatitis, HIV or other infectious agents, therefore has to take all necessary precautions for handling potentially infectious.

NOTE

- Inaccurate results, discoloration of the reagent or loss vacuum in the vials could indicate a deterioration of product. In any case, poor performance of control could also be due to other factors related to the dosing system.
- For in vitro diagnostic use only.

WASTE DISPOSAL

Product is intended for professional laboratories.
Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE CG-CN
Normal control 5 x 1 ml (liophile)

CODE CG-CP
Pathological control 5 x 1 ml (liophile)

REFERENCES

NCCLS: One – Stage Prothrombin Time (PT) Test and Activated Partila Thromboplastin Time (APTT) Test; Approved Guideline. NCCLS document H47 – A, NCCLS, Wayne PA, (1996).
NCCLS Collection, Transport and Procvessing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays 2nd edition. Approved guideline. NCCLS Document H21 – A3. Wayne, PA (1998).

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