



Coagulation Calibrator

Reference plasma for calibration of coagulation tests

Lot: 1705217880

USE

Coagulation Calibrator may be used for calibration of global tests (prothrombin time and fibrinogen) and specific tests such as coagulation factors and other proteins.

PROVIDED REAGENTS

Calibrator: citrated plasma pool from healthy patients. Lyophilized

NON-PROVIDED REAGENTS

- Distilled water

INSTRUCTIONS FOR USE

- Let stand at room temperature and carefully open the vial to prevent loss of the lyophilized material.
- Add 1.0 ml of distilled water
- Cover and let stand for 30 minutes at room temperature. Mix by gentle rotation until complete reconstitution, avoiding foaming.
- Mix by inversion immediately before use.

WARNINGS

Reagent is for "in vitro" diagnostic use.
The plasma was prepared from non-reactive material for HBsAg, antibodies to HCV and antibodies to HIV 1+2. Nonetheless, the calibrator and all blood samples should be handled as if capable of transmitting infections.
Use the reagents according to the working procedures for clinical laboratories.
The reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

Stable in refrigerator (2-10°C) until the expiration date shown on the box. Once reconstituted the reagent is stable for 4 hours at room temperature (< 25°C). Do not freeze (-20°C) after reconstitution due to possible activity loss.

PROCEDURE

The reconstituted plasma should be used in the same way as an unknown sample, according to the instructions provided with the kit of reagents that are used in each case.

PROCEDURE LIMITATIONS

Failures in reconstitution or preservation may cause erroneous results.

See Procedure Limitations in the corresponding Instruction Manual of the kit in use.

WIENER LAB PROVIDES

- 5 x 1 ml (Cat. Nº 1705007)

REFERENCES

- Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline. EP15-A2, Vol. 25, Nº 17, NCCLS.
- User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline. EP12-A, Vol. 22, Nº 14, NCCLS.
- Evaluation of Stability of In Vitro Diagnostic Reagents. Approved Guideline. EP-25A, Vol. 29, Nº 20, CLSI (ex NCCLS).
- Tietz Textbook of Clinical Chemistry, Saunders Co., 3rd ed. (1999).

ASSIGNED VALUES			
Test	Reagent	Value	Unit
Prothrombin activity	Soluplastin	110	%
Fibrinogen	Fibrinógeno	336	mg/dl

Symbols

The following symbols are used in the packaging for Wiener lab. diagnostic reagent kits.



This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices



Authorized representative in the European Community



"In vitro" diagnostic medical device



Contains sufficient for <n> tests



Use by



Temperature limitation (store at)



Do not freeze



Biological risks



Volume after reconstitution



Contents



Batch code



Manufactured by:



Harmful



Corrosive / Caustic



Irritant



Consult instructions for use



Calibrator



Control



Positive Control



Negative Control



Catalog number

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