Plasma Control

Patológico

For precision control in coagulation

Lot: 1712235620

USES
The **Plasma Control Patológico** is designed to be used as control of the determination of prothrombin time, thrombin time, activated partial thromboplastin time and fibrinogen.

PROVIDED REAGENTS
Patologic Control: lyophilized pool of normal human plasmas obtained with citrate as anticoagulant, processed to obtain abnormally extended prothrombin, thrombin, and activated partial thromboplastin times and low concentration of fibrinogen.

NON-PROVIDED REAGENTS
Bidistilled or deionized water.

INSTRUCTIONS FOR USE
Reconstitute each vial with 1.0 ml bidistilled or deionized water. Allow this material to dissolve for 20 minutes at room temperature, mixing without inversion. Make sure that all particles are completely dissolved.

WARNINGS
Reagent is for “in vitro” diagnostic use.
The patologic control has been prepared from material non-reactive for HBsAg, HCV and HIV. However, the control and all other blood samples should be handled as potentially infectious biological material.
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
The patologic control is stable in refrigerator (2-10ºC) until the expiration date indicated on the box.
Once reconstituted, it is stable for 8 hours both at room temperature and refrigerated (2-10ºC).

INSTABILITY OR DETERIORATION OF REAGENTS
Any variation in the color of the patologic control may be a sign of deterioration.

PROCEDURE
Reconstituted patologic contro is used in the same way as an unknown sample, according to the instructions attached to the kit of reagents for prothrombin time, thrombin time, activated partial thromboplastin time and fibrinogen used.

PROCEDURE LIMITATIONS
Mistakes when reconstituting the reagent may cause erroneous results.
See LIMITATIONS OF THE PROCEDURE on the package insert of the kit in use.

REFERENCE VALUES
The values for prothrombin time, thrombin time, activated partial thromboplastin time and fibrinogen, using Plasma Control, depend on the reagents and coagulation analyzers in use.

WIENER LAB. PROVIDES
- 6 x 1 ml (Cat. Nº 1937002)

REFERENCES

- Tietz, N. W. (Ed): Fundamentals of Clinical Chemistry, W. B. Saunders Co., Philadelphia, 865 (1982)
- Young, D.S., Effects of preanalytical variables on clinical laboratory test. AACC Press. Third ed. (2007).

Reagent	Method	Mean	Acceptable Range	
Soluplastin (sec)	Manual	46.0	34.5	57.5
	CoL Series	46.0	34.5	57.5
	COR 50	49.0	36.8	61.3
Soluplastin (%)	Manual	18.5	13.9	23.1
	CoL Series	18.5	13.9	23.1
	COR 50	18.5	13.9	23.1
APTTest (sec)	Manual	62.4	46.8	78.0
APTTest ellágico (sec)	Manual	62.0	46.5	77.5
	CoL Series	62.0	46.5	77.5
	COR 50	64.0	48.0	80.0
Fibrinógeno (mg/dL)	Manual	148	118	178
	CoL Series	148	118	178
	COR 50	148	118	178
Fibrinogen Turbitest AA (mg/dL)	(*)	153	122	184
Tiempo de Trombina 4.0 UNIH/mL (sec)	Manual	16.2	13.0	19.4
	CoL Series	16.0	12.8	19.2
	COR 50	16.0	12.8	19.2
Tiempo de Trombina 2.7 UNIH/mL (sec)	Manual	20.0	16.0	24.0
	CoL Series	20.2	16.2	24.2
	COR 50	20.7	16.6	24.8

(*) Turbidimetric method in automated analyzers.

Symbols

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

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

EC REP — Authorized representative in the European Community

IVD — "In vitro" diagnostic medical device

Contains sufficient for <n> tests


Use by


Temperature limitation (store at)


Do not freeze


Biological risks


Volume after reconstitution

Cont. — Contents

LOT — Batch code


Manufactured by:


Harmful


Corrosive / Caustic


Irritant


Consult instructions for use

Calibr. — Calibrator

CONTROL — Control

CONTROL + — Positive Control

CONTROL − — Negative Control

REF — Catalog number

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