



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 (2-10°C) until the expiration date indicated on the box.

Once reconstituted, it is stable for 8 hours both at room temperature and refrigerated (2-10°C).

INSTABILITY OR DETERIORATION OF REAGENTS

Any variation in the color of the patologic control may be a sign of deterioration.

PROCEDURE

Reconstituted patologic control 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. N° 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
APTTTest (sec)	Manual	62.4	46.8	78.0
APTTTest 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

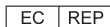
The following symbols are used in the packaging for Wiener lab. diagnostic reagent kits.



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



Manufactured by:



Authorized representative in the European Community



Harmful



"In vitro" diagnostic medical device



Corrosive / Caustic



Contains sufficient for <n> tests



Irritant



Use by



Consult instructions for use



Temperature limitation (store at)



Calibrator



Do not freeze



Control



Biological risks



Positive Control



Volume after reconstitution



Negative Control




Contents



Batch code



Catalog number

 Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 - Rosario - Argentina
<http://www.wiener-lab.com.ar>
Dir. Téc.: Viviana E. Cétola
Biochemist
A.N.M.A.T. Registered product
Cert. N°: 1622/96



Wiener lab.

2000 Rosario - Argentina