

Normal Lot: 509043 Exp.: 22/06/08  
Pathologic Lot: 407078 Exp.: 29/04/07

**Lyophilized plasma for control precision and accuracy in coagulation**

### USES

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

### PROVIDED REAGENTS

**Normal Control Plasma:** lyophilized pool of normal plasmas obtained with citrate as anticoagulant.

**Pathologic Control Plasma:** lyophilized pool of normal 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

Reagents are for "in vitro" diagnostic use.

These Control Plasmas have been prepared from material non-reactive for HBsAg, HCV and HIV. However, controls and all other blood samples should be handled as potentially infectious biological material.

### STABILITY AND STORAGE INSTRUCTIONS

The Control Plasmas as provided, are stable in refrigerator (2-10°C) until the expiration date indicated on the box. Once reconstituted, they are 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 Control Plasma may be a sign of deterioration.

### PROCEDURE

Reconstituted Control Plasmas are 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 Control Plasmas 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 Control Plasmas, depend on the reagents and coagulation analyzers in use.

### Manual Technique

Reagent	Normal Control Plasma	Pathologic Control Plasma
Prothrombin Time	9.3 - 13.5 seg	18.8 - 25.4 seg
APTT	28.1 - 46.9 seg	62.1 - 84.0 seg
APTT ellagic	27.0 - 40.4 seg	47.9 - 68.9 seg
Fibrinogen	237 - 341 mg/dl	125 - 181 mg/dl
Thrombin Time		
4.0 UNIH/ml	12.7 - 18.3 seg	10.9 - 15.7 seg
2.7 UNIH/ml	15.6 - 22.4 seg	13.5 - 19.5 seg

### Automated Technique\*

Reagent	Normal Control Plasma	Pathologic Control Plasma
Prothrombin Time	9.1 - 13.1 seg	18.8 - 25.4 seg
APTT	28.1 - 46.9 seg	62.1 - 84.0 seg
APTT ellagic	27.0 - 40.4 seg	47.9 - 68.9 seg
Fibrinogen	237 - 341 mg/dl	125 - 181 mg/dl
Thrombin Time		
4.0 UNIH/ml	12.7 - 18.3 seg	10.9 - 15.7 seg
2.7 UNIH/ml	15.6 - 22.4 seg	13.5 - 19.5 seg

\*Coa DATA coagulation instruments

### KIT SIZE

- Normal Control Plasma: 6 x 1 ml (Cat. N° 41005).
- Pathologic Control Plasma: 6 x 1 ml (Cat. N° 41006).



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