

Pacific Hemostasis®

Abnormal Thrombin Time Control

I. Intended Use

Pacific Hemostasis Abnormal Thrombin Time Control is a citrated human plasma intended for use in the quality control of the Thrombin Time (TT) test.

II. Summary

Fibrinogen (Factor 1) is a soluble plasma protein that is instrumental in the normal coagulation process. Following trauma or injury, fibrinogen is converted to an insoluble fibrin clot by a two-stage process. In stage one, thrombin cleaves fibrinogen to form a fibrin monomer. In stage two, these fibrin monomers aggregate to form the insoluble fibrin polymers that are recognized as the end point in thrombin clotting assays.

The Thrombin Time is a simple test to screen for conditions that can interfere with the conversion of fibrinogen to fibrin. A thrombin reagent (low thrombin concentration) is added to undiluted plasma and clot formation is timed. The TT may be prolonged when any of the following conditions exists:

- Decreased fibrinogen levels
- Dysfunctional fibrinogen molecules (dysfibrinogenemia)
- Heparin therapy
- Increased Fibrinogen Degradation Products (FDP)
- Presence of abnormal serum globulins or increased immunoglobulins ^(1,2)

Pacific Hemostasis Abnormal Thrombin Time Control is a control containing low levels of fibrinogen and giving a prolonged thrombin time. Using both normal and abnormal thrombin time control plasmas ensure that the test system is working properly.

III. Reagent

Abnormal Thrombin Time Control is a lyophilized preparation of fresh human citrated plasma containing a decreased level of fibrinogen, with added buffers and stabilizers. The lyophilized Abnormal Thrombin Time Control is stable until the date indicated on the label if stored at 2-8°C.

Reconstitute with 1.0 mL distilled water. Swirl gently and let stand undisturbed for 15 minutes at room temperature. Following proper reconstitution, the Abnormal Thrombin Time Control Plasma is stable for 24 hours when stored in a capped vial at 2-8°C.

For *in vitro* diagnostic use.

Caution: Each unit of source material used in the preparation of this product has been tested by an FDA approved method and found non-reactive for HB_sAg (Hepatitis B Surface Antigen) and negative for antibodies to HIV and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit hepatitis, AIDS, or other infectious diseases. This product, like all materials of human origin, should be handled as potentially infectious biological material.

IV. Procedure

Reconstituted Abnormal Thrombin Time Control Plasma should be handled in the same manner as patient specimens.

Incubate 0.2 mL undiluted plasmas at 37°C for 3 minutes. Add 0.1 mL Pacific Hemostasis Thrombin Time reagent and time the clot formation.

V. Expected Values

Actual limits of quality control acceptability should be determined by each laboratory. Listed below are typical values for Pacific Hemostasis Abnormal Thrombin Time Control plasma.

Pacific Hemostasis Abnormal Thrombin Time Control	Thrombin Time (Seconds)	
	MLA®Electra-1600C™	BBL®Fibrometer®
Lot #A	18.1	20.9
Lot #B	18.2	20.5
Lot #C	16.5	19.4

VI. Limitations

This product is designed as a control for monitoring Thrombin Time testing. When used properly, the control is subject to the limitations of the testing system. Deviations in control values may indicate problems with one or more of the components in the test system.

VII. Reference

1. Bick, R.L. et al. *Hematology, Clinical and Laboratory Practice*. Vol Two. Mosby, 1993, pp 1309-1315.
2. Powers, L.W. *Diagnostic Hematology, Clinical and Technical Principles*. Mosby, 1989, pp 485.

Ordering Information








Cat. No.	Description	Contents
100013	Abnormal Thrombin Time Control	10 x 1 mL
100595	Coagulation Control Plasma, Level 1	10 x 1 mL
100011	Thrombin Time Reagent	10 x 1 mL


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Symbols Key

	Manufacturer
	In Vitro Diagnostic Medical Device
	Lot Number
	Use By
	Temperature Limitation
	Catalogue Number
	Consult Instructions for Use

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Rev. (R1)

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