

PRODUCT DESCRIPTION

Thrombolytic Control Plasma™ is prepared from human plasma to simulate plasma from patients treated with streptokinase or urokinase. This lyophilized control plasma contains elevated levels of Fibrinogen Degradation Products (FDP) and decreased levels of fibrinogen and plasminogen, characteristic of plasma from patients in the lytic state.^{1,5}

INTENDED USE

Thrombolytic Control Plasma is used as a therapeutic level control in tests for monitoring thrombolytic therapy. When assayed in the same manner as a patient plasma, it serves to verify sensitivity and precision in the critical therapeutic range of the test system in use.

PRINCIPLE

Streptokinase and urokinase are the drugs most frequently used in thrombolytic therapy. While the mechanisms by which these drugs initiate fibrinolysis differ, they ultimately induce similar biochemical changes in blood. Collectively, these changes are referred to as the lytic state. Attainment of the lytic state is required to assure the potential for successful thrombolysis.^{2,5}

The lytic state can be characterized by increased levels of fibrinogen degradation products, decreased fibrinogen and decreased plasminogen. Thrombolytic therapy is monitored with tests which are sensitive to the concentrations of these plasma constituents. Laboratory assays employed for this purpose include the thrombin time, FDP titer, fibrinogen, plasminogen and Reptilase® time.^{1,3,4,5}

The Thrombolytic Control Plasma has been prepared to yield assay values similar to those of patients treated with streptokinase or urokinase. Incorporation of this control into the assay procedure will serve to alert the laboratorian to possible inaccuracies in the therapeutic range of the test system in use.

PRECAUTIONS

Thrombolytic Control Plasma is FOR IN VITRO DIAGNOSTIC USE ONLY and is NOT FOR INJECTION OR INGESTION. The plasma has been tested at the source and found negative for Hepatitis B Surface Antigen (HBsAG) and non-reactive for HIV and HCV by a FDA approved test. However, all plasma of human origin should be handled as being potentially hazardous.

MATERIALS PROVIDED

Thrombolytic Control Plasma, 5 X 1.0mL.
Store at 2°-8°C prior to reconstitution.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Purified water (distilled, deionized, or reagent grade), pH 5.3 - 7.2
2. Pipette (1.0mL volume capacity)

INSTRUMENTATION

Thrombolytic Control Plasma may be used for quality assurance in tests of fibrinolysis on a manual basis or on automated or semiautomated instrumentation. Follow the manufacturer's instructions for operating the instrument in use.

RECONSTITUTION

1. Tap the vial to dislodge any material adhering to the stopper.
2. Open vial and add 1.0mL of purified water.
3. Close vial and let stand at room temperature for 10 minutes.

NOTE: Reconstituted plasma is stable for 18 hours when stored at 2°-8°C.

QUALITY CONTROL PROCEDURE

1. Assay the Thrombolytic Control Plasma in the same manner as citrated patient plasma in tests for monitoring thrombolytic therapy.
2. Calculate test results for Thrombolytic Control Plasma (if necessary) as if it were a patient specimen.
3. Compare test results obtained with Thrombolytic Control Plasma to the expected results for the test method in use (see EXPECTED RESULTS).

EXPECTED RESULTS

Thrombolytic Control Plasma is tested with FDA approved assay systems to assure that the material will provide abnormal values for Thrombin Time, Plasminogen, Fibrinogen, and FDP. Factors such as methodology, instrumentation and technique, however, contribute to inter-laboratory variation in these values. **Therefore, it is recommended that each laboratory establish its own acceptance ranges with each new lot of Thrombolytic Control Plasma.**

LIMITATIONS

Thrombolytic Control Plasma, when used as directed, will provide analyte results comparable to those found in patients undergoing lytic therapy. However, results can be influenced by instrument function, procedural technique and reagent reconstitution.

PERFORMANCE CHARACTERISTICS

When assayed by the following methods, Thrombolytic Control Plasma yielded reproducible values commensurate with those anticipated from patients treated with fibrinolytic drugs.

PROCEDURE	EXPECTED RESULTS
Thrombin Time	Thrombin Clotting Time™, Thrombinex® Optical Methods > 2 x Normal Plasma Reference Interval
Plasminogen	Chromogenic Methods < Normal Plasma Reference Interval
Fibrinogen	Kinetic Fibrinogen Assay (KFA™) < 150 mg/dL von Claus Methods < 100 mg/dL
FDP	Latex Methods > Normal Plasma Reference Interval

REFERENCES

1. Barlow GH, Robbins KC: Fibrinolytic agents. In Colman RW, Hirsh J, Marder VJ, Salzman EW: Hemostasis and thrombosis: 1028, J.B. Lippincott Company, Philadelphia, 1982.
2. Bell WR, Meek AG: Guidelines for the use of thrombolytic agents. N Engl J Med, 301(23):1266, 1979.
3. Cash JD: Monitoring fibrinolysis. Postgraduate Med J (Aug Suppl):37, 1973.
4. Conard J, Samama M: Laboratory control of SK therapy. Thromb Diath Haemorrh (Suppl) 56:191, 1973.
5. Marder VJ, Bell WR: Fibrinolytic therapy. In Colman RW Hirsh J, Marder VJ, Salzman EW: Hemostasis and thrombosis: 1037, J.B. Lippincott Company, Philadelphia, 1982.

PRODUCT AVAILABILITY

Product	Catalog Number	Net Contents
Thrombolytic Control Plasma™	101625	5 X 1.0mL

ALSO AVAILABLE

Thrombin, Bovine, Thrombinex®	101628	20 X 2.0mL
Thrombin Clotting Time	101283	50 Determinations
Low Fibrinogen Control	101303	5 X 1.0mL
Assayed Reference Plasma, Normal	105099	10 X 1.0mL
Assayed Reference Plasma, Abnormal	105102	10 X 1.0mL

This product is warranted to perform as described in the labeling and in the literature of Bio/Data Corporation and BIO/DATA CORPORATION DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY OTHER PURPOSE, AND IN NO EVENT SHALL BIO/DATA CORPORATION BE LIABLE FOR ANY CONSEQUENTIAL DAMAGES ARISING OUT OF AFORESAID EXPRESSED WARRANTY.



155 Gibraltar Road, PO Box 347,
Horsham, PA 19044-0347 U.S.A.
(800) 257-3282 USA (215) 441-4000 Worldwide
(215) 443-8820 Fax Worldwide
E-Mail: bdc@biodatacorp.com
Internet: www.biodatacorp.com