



CITREX® I

Normal Control Plasma

PRODUCT DESCRIPTION

Citrex I is a lyophilized preparation of human plasma. Citrex I is normal plasma collected in a citrate anticoagulant and buffered to ensure stability.

INTENDED USE

Citrex I is a control plasma for quality assurance in prothrombin time (PT), and activated partial thromboplastin time (APTT) testing.

PRINCIPLE

The precision and accuracy of prothrombin times and activated partial thromboplastin times can be affected by a number of factors. Intralaboratory variables which may impact results include: pH of the purified water used for reagent preparation, pipetting techniques, incubation time and temperature, reagent contamination, and changes in reagent lot numbers.¹ Significant interlaboratory differences arise from the variety of methods used to measure coagulation endpoints.² Periodic quality control analyses, performed on a regular basis with Citrex I, II, and III, will serve to identify the occurrence of deviations which may lead to erroneous test results.

PRECAUTIONS

Citrex I is FOR IN VITRO DIAGNOSTIC USE ONLY and is NOT FOR INGESTION OR INJECTION. The plasma has been tested at the source and found to be negative for Hepatitis B Surface Antigen (HB_sAG) and nonreactive for HIV and HCV by an F.D.A. approved test. However, all plasma of human origin should be handled as being potentially hazardous.

MATERIALS PROVIDED

Citrex I (Normal)
Each Package contains 20 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)

RECONSTITUTION

1. Tap the vial to dislodge material adhering to the stopper.
2. Remove the aluminum seal.
3. Remove the stopper and reconstitute the vial contents with the volume of purified water specified on the label.
4. Replace the stopper and swirl the vial to thoroughly disperse the contents. Let stand for no less than 15 minutes prior to use to assure complete rehydration of the contents.

Once reconstituted, Citrex I is stable for 36 hours when stored at 2° - 8° C in the tightly stoppered original polypropylene vial. Allow to warm to room temperature prior to reconstitution.

QUALITY CONTROL

1. Citrex I is tested in the same manner as citrated patient plasma in prothrombin times and activated partial thromboplastin times.
2. Compare test results obtained to the expected results for the test method and control plasma in use (see EXPECTED RESULTS).

EXPECTED RESULTS

For each test of coagulation, influences such as methodology, instrumentation and technique contribute to possible variation in results.⁴ Therefore, it is recommended that each laboratory establish its own acceptance ranges with each new lot of Citrex I and/or any related reagents by performing replicate studies.

Citrex I may yield results within the reference range in prothrombin times and activated partial thromboplastin times. Results may vary with test method.

TEST	CLOTTING TIME (seconds) CITREX I
Prothrombin Time (Plastinex® Thromboplastin Reagent)	11 - 14
Activated Partial Thromboplastin Time (Cephalinex® APTT Reagent)	27 - 37

INTERPRETATION

Should test results obtained with Citrex I fall outside of acceptable limits, each component of the test system should be evaluated to determine the source of deviation.¹ The following may contribute to erroneous results:

- REAGENT PREPARATION
- RECONSTITUTION OF CITREX I
- PROCEDURAL VARIATIONS
- INSTRUMENTATION

PERFORMANCE CHARACTERISTICS

The coefficient of variation (C.V.) for prothrombin times and activated partial thromboplastin times performed on Citrex I has been demonstrated to be less than 7% for intralaboratory studies. However, precision characteristics will vary depending on the coagulation instrumentation and reagent system in use.

REFERENCES

1. Harms CS: Coagulation pretesting variables and quality control. In Triplett DA: Laboratory evaluation of coagulation, pg 350, American Society of Clinical Pathologists Press, Chicago, 1982.
2. Triplett DA: Evatt BL, van den Besselaar AMHP. Proficiency testing and standardization of prothrombin time: potential use of thromboplastin calibration in the United States. In van den Besselaar AMHP, Gralnick HR, Lewis SM: Thromboplastin calibration and oral anticoagulant control, pg 209, Martinus Nihoff Publishers, Boston, 1994.
3. Gralnick HR, Evatt BL, Huseby RM, Triplett DA: Procedural standards for the prothrombin time. In Triplett DA: Standardization of coagulation assays: an overview, pg 51. College of American Pathologists, Skokie, 1982.
4. Sabo MG: Coagulation Instrumentation And Reagent Systems. In Triplett DA: Laboratory Evaluation Of Coagulation, pg 316, American Society of Clinical Pathologist Press, Chicago, 1982.
5. Westgard JO, Barry PL, Hunt MR, Groth T: A multi-rule Shewhart chart for quality control in clinical chemistry. Clin. Chem. 27 (3), 493-501, 1981.
6. Mackie MJ, Douglas AS: Drug Induced Disorders of Coagulation, pg 493 In: Ratnoff OD, Forbes CD (eds.): Disorders of Hemostasis W. B. Saunders Co. 2d Ed., Philadelphia, 1991.

PRODUCT AVAILABILITY

PRODUCT	NET CONTENTS	CATALOG NUMBER
Coagulation Control Plasma		
Citrex® I (Normal)	20 x 1.0mL	101166
Citrex II (Abnormal)	20 x 1.0mL	101170
Citrex III (Abnormal)	20 x 1.0mL	101174
Plastinex®		
Thromboplastin Reagent	20 x 4.0mL	101158
	15 x 10.0mL	102672
Cephalinex®		
APTT Reagent (<i>Silica Activated</i>)	20 x 3.0mL	101162
	15 x 10.0mL	102677
Thrombinex® (Bovine Thrombin)	20 x 2.0mL	101628
Calcium Chloride Solution 0.025M	1 x 473mL	100989

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 U.S.A. (215) 441-4000 Worldwide
(215) 443-8820 Fax Worldwide
E-mail: bdc@biodatacorp.com
Internet: www.biodatacorp.com