

PRODUCT DESCRIPTION

Citrex II and III are lyophilized preparation of human plasma. Citrex II and III have been selectively depleted of the Vitamin K dependent coagulation factors. All of the plasmas are collected in citrate anticoagulant and buffered to ensure stability.

INTENDED USE

Citrex II and III are control plasmas for quality assurance in prothrombin time (PT) and activated partial thromboplastin time (APTT) testing. Citrex II and III verify test performance in the moderately and extremely extended ranges of coagulation, respectively.

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 II and III, will serve to identify the occurrence of deviations which may lead to erroneous test results.

PRECAUTIONS

Citrex II and III are FOR IN VITRO DIAGNOSTIC USE ONLY and are 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. All plasma of human origin should be handled as being potentially hazardous.

MATERIALS PROVIDED

Citrex II (Abnormal) or
 Citrex III (Abnormal).
 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. Pipettes (1.0mL volume capacity)

RECONSTITUTION

1. Tap the vial to dislodge material adhering to the stopper.
2. Remove the aluminum seal by lifting the plastic safety cap.
3. Remove the stopper and reconstitute the vial contents with the volume of purified water specified on the label.
4. Replace the stopper and mix 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 II and III are stable for 36 hours when stored at 2° - 8° C in the tightly-stoppered original polypropylene vial.

QUALITY CONTROL

1. Citrex II and III are tested in the same manner as citrated patient plasma in prothrombin times and activated partial thromboplastin times.³
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 coagulation test, 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 limits with each new lot of Citrex and/or any related reagents, by performing replicate studies.

Citrex II and III will yield results in the moderately and extremely prolonged ranges, respectively, for prothrombin times and activated partial thromboplastin times.

TEST	CLOTTING TIME (SECONDS)	
	CITREX II	CITREX III
Prothrombin Time (Plastinex® Thromboplastin)	17 - 22	24 - 38
Activated Partial Thromboplastin Time (Cephalinex® APTT Reagent)	50 - 70	75 - 110

INTERPRETATION

Should test results obtained with Citrex II or III 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:

INSTRUMENTATION
 REAGENT PREPARATION
 RECONSTITUTION OF CITREX I
 PROCEDURAL VARIATIONS

PERFORMANCE CHARACTERISTICS

The coefficient of variation (C.V.) for prothrombin times and activated partial thromboplastin times performed on Citrex II and III 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, Granick HR, Lewis SM: Thromboplastin calibration and oral anticoagulant control, pg 209, Martinus Nihoff Publishers, Boston, 1994.
3. Granick HR, Evatt BL, Huseby RM, Triplett DA: Procedural standards for the prothrombin time. In Triplett DA: Standardization of coagulation of 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 coagulant, 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
Citrex® II	20 x 1.0mL	101170
Citrex III	20 x 1.0mL	101174

ALSO AVAILABLE

Citrex I	20 x 1.0mL	101166
Cephalinex®, APTT	20 x 3.0mL	101162
Reagent (Silica Activated)	15 x 10.0mL	102677
Plastinex®	20 x 4.0mL	101158
Thromboplastin Reagent	15 x 10.0mL	102672
Thrombinex® (Bovine Thrombin)	20 x 2.0mL	101628
Calcium Chloride Solution 0.025M	1 x 473mL	100989

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