Dade® Ci-Trol® Coagulation Control Level 1
Ci-Trol CONTROL 1

Revision bar indicates update to previous version.

CE 0197

Intended Use

The use of controls in the coagulation laboratory is an established procedure. Ci-Trol CONTROL 1 is recommended as a normal control with patient citrated plasma for prothrombin time (PT) and activated partial thromboplastin time (APTT) determinations yielding values similar to those of fresh normal plasma. This product may also be used as a fibrinogen control for fibrinogen determinations using the Dade® Thrombin method.

Reagents

Reagent	Description	Storage	Stability
Dade® Ci-Trol® Coagulation Control Level 1 Ci-Trol CONTROL 1	Lyophilized reagent containing: • human plasma • Stabilizer • Buffer	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	2–8 °C: reconstituted, 16 hours[a]; 15–25 °C: reconstituted, 8 hours[a]

[a] closed original vial

Indications of deterioration: lack of vacuum upon opening vial or inability to obtain reproducible values.

Warnings and Precautions

For *in-vitro* diagnostic use only.

For laboratory professional use.

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State through your local distribution representative in which the user and/or patient is established.

Safety data sheets (MSDS/SDS) available upon request.

Caution! Potential Biological Risk
Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, hepatitis B virus (HBV) and hepatitis C virus (HCV) using either tests that are CE marked or FDA approved for this purpose. Because no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with appropriate caution.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all government requirements.

Summary of Safety and Performance (SSP) is available in the European database on medical devices (see Eudamed public website: https://ec.europa.eu/tools/eudamed). In case Eudamed is not available, SSP can be delivered by the manufacturer on request.

Preparing Reagents

Add exactly 1 mL of distilled water, gently tilt the vial and allow 15 minutes for reconstitution of the plasma in the closed vial.

Before use, gently mix once more.

Do not shake.

Note: Do not use distilled water containing preservatives.

Procedure

Materials Provided

REF	Contents	
B4244-10	Dade® Ci-Trol® Coagulation Control Level 1 Ci-Trol CONTROL 1 Table of Assigned Values	20 × → 1 mL

Materials Required but not Provided

Item	Description
Coagulation analyzers[b], such as:	• Automated Blood Coagulation Analyzer CA-600 series (CA-600 series) • AUTOMATED BLOOD COAGULATION ANALYZER CS-2500 (CS-2500 System) • AUTOMATED BLOOD COAGULATION ANALYZER CS-5100 (CS-5100 System) • Automated Blood Coagulation Analyzer CN-3000/CN-6000 (CN-3000/CN-6000 System)

[b] Availability of analyzers may vary by country.

Please note that the applications on other analyzers can be validated by the instrument manufacturer in accordance with the requirements of the REGULATION (EU) 2017/746 under their responsibility as long as the intended purpose and performance are not modified.

After reconstitution, use Ci-Trol CONTROL 1 in the same manner as freshly drawn patient citrated plasma using the same test procedure. Ci-Trol CONTROL 1 can be used in the manual tilt tube method as well as most semi-automated and automated instrument techniques. See instrument operator's manual for detailed instructions and limitations of procedure.

Controls such as Ci-Trol CONTROL 1 should be tested at the initiation of testing, upon reagent changes, and at least once each 8 hour shift. The control material should be run in the same manner as the test samples. Each laboratory should establish a range for control values. If control values are outside of determined range, check controls, reagents, and instrument. It is recommended before reporting any patient data to document any actions taken to identify and correct the problem. New control ranges should be established for each lot of reagent or control material.

Limitations

Inability to obtain proper control values may be a sign of product deterioration. However, when proper control values are not obtained, a study of each component of the test system (i.e., reagents, control and technical conditions) is indicated to ascertain that all other components are functioning properly.

Expected Values

Prothrombin Time (PT)

Ci-Trol CONTROL 1 is specifically designed for use with following PT reagents: Dade® Innovin® and Thromborel® S. Using Dade® Innovin®, the following performance guidelines apply for Ci-Trol CONTROL 1:

Level 1

BCS® System (US setting)	9.6 to 12.6 seconds
CA-1500 System	9.4 to 12.4 seconds

Activated Partial Thromboplastin Time (APTT)

Ci-Trol CONTROL 1 is specifically designed for use with following APTT reagents: Dade® Actin® Activated Cephaloplastin Reagent, Dade® Actin® FS Activated PTT Reagent, Dade® Actin® FSL Activated PTT Reagent and Pathromtin® SL. With these reagents, the APTT mean control values expected with Ci-Trol CONTROL 1 are in the normal range.

Fibrinogen Assay Method

An assigned value for fibrinogen determinations is indicated on the enclosed Table of Assigned Values. Studies indicate that test systems employing the Dade® Fibrinogen method show a typical coefficient of variation (CV) of 2 to 5 %. Laboratories using the product as a control for fibrinogen determinations should expect to achieve this precision.

Mean Assay Value: Mean values are obtained by thrombokinetic reaction using Dade® Thrombin Reagent and Multifibren® U on different Instruments, and by coagulable protein assay. Variations in techniques, equipment, reagents, etc., may result in mean values different from those listed; therefore, each laboratory should establish its own mean values.

Performance Characteristics

Studies of Ci-Trol CONTROL 1 in normal clinical laboratory usage show an intralaboratory variation resulting in a total CV of approximately 3 % for prothrombin times and approximately 4 % for activated partial thromboplastin times.

Since laboratory control materials are used for the effective monitoring of the performance of a coagulation test, each laboratory should establish its own level of performance to monitor quality assurance.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

Definition of Symbols

The following symbols may appear on the product labeling:

	Do not reuse		Use By
LOT	Batch Code	REF	Catalogue Number
	Caution		Manufacturer
EC REP	Authorized representative in the European Community	CH REP	Authorized representative in Switzerland
	Contains sufficient for <n> tests		Biological Risks
IVD	*In Vitro* Diagnostic Medical Device		Temperature Limitation
	Consult instruction for Use		Non-sterile
CE	CE marking of conformity	CE 0197	CE marking of conformity with notified body ID number. Notified body ID number can vary.
CONTENTS	Contents		Reconstitution volume
LEVEL	Level		Keep away from sunlight and heat
WARNING	Warning	DANGER	Danger
RxOnly	Prescription device (US only)	UDI	Device Identification (UDI) barcode
REACH xx/xx/xx	REACH Authorization Number		

Legal Information

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