

Dade® Ci-Trol® 2

I Revision bar indicates update to previous version.

CE0197

Control plasma in the therapeutic range

Intended Use

Dade® Ci-Trol® 2 is used for control of coagulation tests in the middle to upper therapeutic range of oral anticoagulant therapy. With its reduced activities of factors: FII, FVII, FIX and FX, this control is equivalent to plasma from a patient receiving anticoagulant treatment. Dade® Ci-Trol® 2 is preferentially included in each run as an "abnormal plasma" for the control of accuracy and precision. In addition to control values for the prothrombin time (PT), Dade® Ci-Trol® 2 also provides assigned values for the activated partial thromboplastin time (APTT) to enable monitoring for reduced activity of the intrinsic coagulation factors as well as the therapeutic range in heparin therapy. The assigned values were established on mechanical and optical coagulometers using manufacturers reagents. These values were established with reference to an international standard calibrated against pooled citrated plasma.

Reagents

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

^a produced from pooled, fresh citrated human plasma

^b closed original vial

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 1.0 mL of double-distilled water**, then gently tilt the vial and leave to stand for **15 minutes** with the vial closed. Before use, gently mix once more! Dade® Ci-Trol® 2 can be used in the same manner as freshly collected citrated plasma.

Notes on assigned values

Assigned values are calculated with mechanical and optical devices at 37 °C. As a rule, the results obtained (seconds; % of the norm; INR; % activity) should lie within the confidence range indicated in the lot-specific Table of Assigned Values.

However, the results obtain in seconds are especially dependent on the method, the equipment used, the working technique and the specificity of the reagent, and may therefore fall outside the indicated confidence range in exceptional cases.

Procedure

Materials Provided

REF	Contents
291071	Dade® Ci-Trol® 2 Table of lot-specific Assigned Values
	10 × → 1 mL

Materials Required but not Provided

Item	Description
Coagulation analyzers ^c , 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)

^c 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.

Standardization

The reference material and the uncertainty of the Control compared to the reference material are included in the Certificates of Traceability (CoT). The CoTs are available upon request.

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
	Batch Code		Catalogue Number
	Caution		Manufacturer
	Authorized representative in the European Community		Authorized representative in Switzerland
	Contains sufficient for <n> tests		Biological Risks
	<i>In Vitro</i> Diagnostic Medical Device		Temperature Limitation
	Consult instruction for Use		Non-sterile
	CE marking of conformity		CE marking of conformity with notified body ID number. Notified body ID number can vary.
	Contents		Reconstitution volume
	Level		Keep away from sunlight and heat
	Warning		Danger
	Prescription device (US only)		Device Identification (UDI) barcode
	REACH Authorization Number		

Legal Information

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