Dade® Ci-Trol® 1

Revision bar indicates update to previous version.

CE 0197

Control plasma in the normal range

Intended Use

Dade® Ci-Trol® 1 was specially developed as a control for the normal range in coagulation tests with sodium citrate used as the anticoagulant solution, and it is used as a control of precision and accuracy for various reagent systems in the following applications:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (APTT)
3. Thrombin time (TT)
4. Fibrinogen
5. Antithrombin III (ATIII)
6. Batroxobin time/Reptilase time

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® 1	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 normal human plasma

[b] closed original vial

The preparation is produced under careful control to assure that the full activity of the plasma is maintained.

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® 1 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	
291070	Dade® Ci-Trol® 1	10 × → 1 mL
	Table of lot-specific Assigned Values	

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
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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