

Dade® Ci-Trol® Heparin Control, Low

Ci-Trol HEPARIN CONTROL 1

Dade® Ci-Trol® Heparin Control, High

Ci-Trol HEPARIN CONTROL 2

Revision bar indicates update to previous version.

C€0197

Intended Use

For use as a control in heparin assay procedures.

Summary and Explanation

Heparin, an anticoagulant of major therapeutic importance, is recommended for the treatment of thromboembolism, thrombophlebitis, arterial thrombosis and for selected cases of disseminated intravascular coagulation. Several methods are used to monitor the effectiveness of heparin therapy and to regulate dosage of heparin. The use of a stable control plasma is essential in monitoring the performance of the test system.

The activated partial thromboplastin time (APTT) and chromogenic heparin assays have been used to monitor heparin therapy¹⁻⁶ in various clinical applications such as during the treatment of recent venous thrombosis¹ or for the prevention of thrombus formation in high risk patients during surgery². Proper patient management requires accurate and precise APTT test results.

The use of the Ci-Trol HEPARIN CONTROL 1 and Ci-Trol HEPARIN CONTROL 2 in conjunction with Dade® Ci-Trol® Coagulation Controls (Levels 1, 2 and 3) and Dade® Actin® Activated Cephaloplastin Reagent, Dade® Actin® FS or Dade® Actin® FSL Activated PTT Reagent provides a comprehensive Quality Control Program which assures the reproducibility of the test system.

Reagents

Reagent	Description	Storage	Stability
Dade® Ci-Trol® Heparin Control, Low Ci-Trol HEPARIN CONTROL 1	Lyophilized reagent containing: - human plasma, citrated - Heparin sodium, porcine (reconstituted: ≤0.2 U/mL) - buffers/stabilizers	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	2–8 °C: reconstituted, 6 hours
Dade® Ci-Trol® Heparin Control, High Ci-Trol HEPARIN CONTROL 2	Lyophilized reagent containing: - human plasma, citrated - Heparin sodium, porcine (reconstituted: ≤0.6 U/mL) - buffers/stabilizers	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	2–8 °C: reconstituted, 6 hours

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

Ci-Trol [HEPARIN] [CONTROL 1], **Ci-Trol** [HEPARIN] [CONTROL 2]

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.

Caution

Ci-Trol [HEPARIN] [CONTROL 1], **Ci-Trol** [HEPARIN] [CONTROL 2]

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

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

Reconstitute Ci-Trol [HEPARIN] [CONTROL 1] and Ci-Trol [HEPARIN] [CONTROL 2] at room temperature (15 to 25 °C) with 1.0 mL distilled or deionized water for each vial, then close the vial again and let stand for 1 to 2 minutes until the contents are fully dissolved. Swirl lightly until fully dissolved. Do not shake.

Allow the preparation to equilibrate for 15 minutes at 2 to 8 °C before using.

Procedure

Materials Provided

REF	Contents	
B4224-50	Dade® Ci-Trol® Heparin Control, Low Ci-Trol [HEPARIN] [CONTROL 1]	10 × → 1.0 mL
B4224-60	Dade® Ci-Trol® Heparin Control, High Ci-Trol [HEPARIN] [CONTROL 2]	10 × → 1.0 mL

Materials Required but not Provided

Item	Description
Coagulation analyzers ^a , 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)

^a 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.

Following reconstitution and equilibration, the Ci-Trol [HEPARIN] [CONTROL 1] and Ci-Trol [HEPARIN] [CONTROL 2] is used in the same fashion as freshly obtained plasma from patients undergoing heparin therapy with the appropriate reagents according to the instructions in the

corresponding Instructions for Use. Employ the same testing conditions as when testing patient plasmas.

A range of allowable variation should be established for the controls in each laboratory. This range usually is based on ± 2.0 to ± 2.5 standard deviations (SD) from the mean control value. Controls such as Ci-Trol **HEPARIN** **CONTROL** 1 and Ci-Trol **HEPARIN** **CONTROL** 2 should be tested at the initiation of testing, upon reagent changes, and at least once each 8 hour shift. The control material should be treated in the same manner as the test samples. 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.

Results

When used for APTT testing, results of Ci-Trol **HEPARIN** **CONTROL** 1 and Ci-Trol **HEPARIN** **CONTROL** 2 should be recorded as the APTT in seconds. When used for chromogenic heparin assays, results of Ci-Trol **HEPARIN** **CONTROL** 1 and Ci-Trol **HEPARIN** **CONTROL** 2 should be calculated using a calibration curve.

For APTT results, use the following equation to calculate performance guideline ratios:

$$\text{Ratio} = \frac{\text{HPL or HPH APTT (seconds)}}{\text{Mean APTT (seconds) of reference range for healthy donors established for each laboratory}}$$

HPL = Ci-Trol **HEPARIN** **CONTROL** 1

HPH = Ci-Trol **HEPARIN** **CONTROL** 2

Limitations

If coagulation analyzers with other measurement principles are used, the coagulation times obtained may deviate from those predetermined for the allowable range.

Expected Values

Ci-Trol **HEPARIN** **CONTROL** 1 and Ci-Trol **HEPARIN** **CONTROL** 2 may be used as performance controls for APTT testing. Each user must develop his own expected range.

	Ratio
Ci-Trol HEPARIN CONTROL 1 CA-1500 System	1.4–2.2
Ci-Trol HEPARIN CONTROL 2 CA-1500 System	1.8–3.8

Examples of ratios using Actin®, Actin® FSL and Actin® FS Reagents are given below:

	Dade® Actin®	Dade® Actin® FSL	Dade® Actin® FS
Ci-Trol HEPARIN CONTROL 1	1.8	1.6	2.0
Ci-Trol HEPARIN CONTROL 2	2.5	2.5	3.5

Performance Characteristics

Ci-Trol **HEPARIN** **CONTROL** 1 and Ci-Trol **HEPARIN** **CONTROL** 2 are prepared to perform according to the results and within the limits discussed when used as abnormal controls for monitoring heparin therapy.

Precision

Precision studies with Ci-Trol **HEPARIN** **CONTROL** 1 and Ci-Trol **HEPARIN** **CONTROL** 2 yielded a typical coefficient of variation of less than 4 % for the APTT when using Actin® Reagent.

If laboratory control preparations are to be used for effective quality assurance in coagulation tests, then each laboratory should determine the mean value and the standard deviation for its own measuring procedures in order to maintain an appropriate aid for monitoring its own quality control.

Standardization

Certificate of Non-Applicability (CoNA) are available upon request.

Technical Assistance

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

References

1. Basu D, Gallus A, Hirsh J, Cade J. A prospective study of the value of monitoring heparin treatment with the activated partial thromboplastin time. *N Engl J Med.* 1972; 287: 324-7.
2. Gallus AS, Hirsh J, Tuttle RJ, et al. Small subcutaneous doses of heparin in prevention of venous thrombosis. *N Engl J Med.* 1973; 288: 545-51.
3. Hirsh J. *Hosp Prac.* 1975; 10: 53.
4. Hirsh J, O'Sullivan EF, Gallus AS, Martin M. The activated partial thromboplastin time in the control of heparin treatment. *Australas Ann Med.* 1970; 19: 334-7.
5. Sussman IN, Bay M. *Lab Med.* 1974; 5: 36.
6. Fey MF, Lang M, Furlan M, Beck EA. Monitoring of heparin therapy with the activated partial thromboplastin time and chromogenic substrate assays. *Thromb Haemost.* 1987; 58: 853-5.

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		
xx/xx/xx			

Legal Information

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