

Dade® CA System Buffer

CA SYSTEM **BUFFER**



I Revision bar indicates update to previous version.

Intended Use

CA SYSTEM **BUFFER** for coagulation tests and as a rinsing solution for the sample needles of the Sysmex CA/CS/CN Systems.

Summary and Explanation

CA SYSTEM **BUFFER** is an Owren's Veronal Buffer and was specially developed for coagulation tests but can also be used whenever an isotonic barbitol buffer with pH of 7.35 is required.

Reagents

Reagent	Description	Storage	Stability
Dade® CA System Buffer CA SYSTEM BUFFER	Ready to use liquid containing: - Sodium barbiturate (2.84×10^{-2} M) - Sodium chloride (1.25×10^{-1} M) pH 7.35 $\pm$ 0.1	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: once opened, 30 days ^a

^a 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.

Avoid contamination. Visible turbidity and flocculation are signs of microbial contamination.

Not for internal or external use in humans or animals.

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.

Preparing Reagents

CA SYSTEM **BUFFER** is ready for use.

Bring to 15 to 25 °C before use.

Procedure

Materials Provided

REF	Contents
B4265-37	Dade® CA System Buffer CA SYSTEM BUFFER 8 × 250 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.

Instrument-specific details on the use of the CA SYSTEM BUFFER are given in the instruction manuals for the CA Systems as well as in the relevant Reference Guides (Application Sheets) provided by Sysmex.

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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