INNOVANCE® D-Dimer Sample Diluent
INNOVANCE D-Dimer DILUENT

Revision bar indicates update to previous version.

CE

Intended Use

INNOVANCE D-Dimer DILUENT is a buffer solution intended to be used in conjunction with the INNOVANCE® D-Dimer method, for the measurement of samples outside the initial measuring range.

Reagents

Reagent	Description	Storage	Stability
INNOVANCE® D-Dimer Sample Diluent INNOVANCE D-Dimer DILUENT	Ready to use liquid containing: • Buffers, preservatives	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	2–8 °C: once opened, 4 weeks[a]; ≤ –18 °C: once opened, 4 weeks[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.

Danger! INNOVANCE D-Dimer DILUENT
Hazardous ingredient: Imidazole (0.332 % [w/w]).
H360D: May damage the unborn child.
P201: Obtain special instructions before use. **P280**: Wear protective gloves/protective clothing/eye protection/face protection. **P308 + P313**: IF exposed or concerned: Get medical advice/attention.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

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

- INNOVANCE D-Dimer DILUENT is ready for use. Prior to placing on the system: Mix carefully and avoid foam formation.
- INNOVANCE D-Dimer DILUENT is placed on the system prior to testing. Please refer to the Instructions for Use of INNOVANCE® D-Dimer for further details.

Procedure

Materials Provided

REF	Contents		
OPBR03	INNOVANCE® D-Dimer Sample Diluent INNOVANCE D-Dimer DILUENT	10 ×	5 mL

Materials Required but not Provided

Item	Description
REF OPBP03, OPBP07	INNOVANCE® D-Dimer and associated materials according to the INNOVANCE® D-Dimer Instructions for Use.
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)

[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.

- The sample dilution with INNOVANCE D-Dimer DILUENT is conducted automatically by the respective system/analyzer for samples with D-dimer concentrations within the extended measuring range.
- Please refer to the INNOVANCE® D-Dimer Instructions for Use and the respective Application Sheets.

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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