INNOVANCE® D-Dimer Controls
INNOVANCE D-Dimer CONTROLS

Revision bar indicates update to previous version.

CE 0197

Intended Use

INNOVANCE D-Dimer CONTROL 1 and INNOVANCE D-Dimer CONTROL 2 are assayed controls for the assessment of precision and analytical bias in the normal and pathological range for the determination of D-dimer on Sysmex automated blood coagulation analyzers.

Reagents

Reagent	Description	Storage	Stability
INNOVANCE® D-Dimer Controls INNOVANCE D-Dimer CONTROLS			
INNOVANCE D-Dimer CONTROL 1	Lyophilized reagent containing: • human plasma[a] • Preservatives	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 8 hours[b]; 2–8 °C: reconstituted, 7 days[b]; ≤ –18 °C: reconstituted, 4 weeks[c]
INNOVANCE D-Dimer CONTROL 2	Lyophilized reagent containing: • human plasma[a] • Preservatives	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 8 hours[b]; 2–8 °C: reconstituted, 7 days[b]; ≤ –18 °C: reconstituted, 4 weeks[c]

[a] human plasma based product containing D-dimer

[b] closed original vial

[c] Must be frozen in the original containers. Do not refreeze after thawing.

INNOVANCE D-Dimer CONTROL 1 and INNOVANCE D-Dimer CONTROL 2 may be frozen in the original container and thawed again once after reconstitution.

The previous storage time at 15 to 25 °C must not have exceeded 4 hours.

The plasma must be well sealed and frozen as quickly as possible.

Thawing must be completed at 37 °C within a maximum of 10 minutes.

INNOVANCE D-Dimer CONTROL 1 and INNOVANCE D-Dimer CONTROL 2 should not stand for more than 4 hours at 15 to 25 °C after thawing.

INNOVANCE D-Dimer CONTROL 1 and INNOVANCE D-Dimer CONTROL 2 must no longer be used if they contain visible clots.

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.

Warning! INNOVANCE D-Dimer CONTROL 1
Hazardous ingredient: Sodium azide (0.631 % [w/w]), reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one / 2-methyl-2H-isothiazol-3-one (3:1) (0.00688 % [w/w]).

Warning! INNOVANCE D-Dimer CONTROL 2
Hazardous ingredient: Sodium azide (0.632 % [w/w]), reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one / 2-methyl-2H-isothiazol-3-one (3:1) (0.00688 % [w/w]).
H317: May cause an allergic skin reaction. **H412**: Harmful to aquatic life with long lasting effects. **P261**: Avoid breathing dust. **P280**: Wear protective gloves/protective clothing/eye protection/face protection. **P273**: Avoid release to the environment. **P302 + P352**: IF ON SKIN: Wash with plenty of soap and water. **P333 + P313**: If skin irritation or rash occurs: Get medical advice/attention. **P362 + P364**: Take off contaminated clothing and wash it before reuse. **P501**: Dispose of contents and container in accordance with all local, regional, and national regulations.

CAUTION! POTENTIAL BIOHAZARD
INNOVANCE D-Dimer CONTROL 1**, INNOVANCE D-Dimer** 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
INNOVANCE D-Dimer CONTROL 1**, INNOVANCE D-Dimer** 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

- Disolve INNOVANCE D-Dimer CONTROL 1 and INNOVANCE D-Dimer CONTROL 2 with 1 mL of distilled water each.
- Shake carefully to dissolve (without foam formation).
- Allow to stand at 15 to 25 °C for at least 15 minutes.
- Before use, again shake carefully.

Procedure

Materials Provided

REF	Contents	
OPDY03	INNOVANCE® D-Dimer Controls INNOVANCE D-Dimer CONTROLS	
	INNOVANCE® D-Dimer Control 1 INNOVANCE D-Dimer CONTROL 1	5 × → 1 mL
	INNOVANCE® D-Dimer Control 2 INNOVANCE D-Dimer CONTROL 2	5 × → 1 mL
	Table of lot- and method-specific Assigned Values and Ranges	

Materials Required but not Provided

Item	Description
REF OPBP03, OPBP07	INNOVANCE® D-Dimer
–	Distilled water
–	Pipettes
Coagulation analyzers[d], 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)

[d] 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.

For quality control, INNOVANCE D-Dimer CONTROL 1 and INNOVANCE D-Dimer CONTROL 2 is used with the INNOVANCE® D-Dimer kit according to the Instructions for Use. The value obtained must be within the range as indicated in the lot-specific Table of Assigned Values.

Determination of assigned values

The target values were assigned by the manufacturer by using INNOVANCE® D-Dimer Calibrator and the corresponding INNOVANCE® D-Dimer reagents. The mean values of the series of determinations performed over several days with different instruments and reagent lots are indicated in the lot-specific Table of Assigned Values.

The range is a fixed interval that covers the systematic analytical deviations that may occur due to deviations in reagents or analyzers.

The method-dependent target values and ranges for each lot of INNOVANCE D-Dimer CONTROL 1 and INNOVANCE D-Dimer CONTROL 2 are provided in the accompanying Table of Assigned Values. If used as a precision control, the user should establish the target concentration and confidence limits during a preliminary phase. Due to performance variability, the use of methods other than those stated in the accompanying Table of Assigned Values is not recommended.

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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