OPERATOR'S MANUAL

NIHON KOHDEN

D-dimer Control
DD-QC

General

Intended Purpose

For in vitro diagnostic use only.

D-dimer Control is control product designed and assigned value to monitor D-dimer assay of Nihon Kohden clinical chemistry analyzers. D-dimer Control is intended to use laboratory professional use only. D-dimer Control is intended for use in conjunction with Celltac chemi D-dimer only and be used for ensuring that the analyzer is functioning according to its intended use.

Devices Intended for Use in Combination with

- MEK-1303 automated hematology and clinical chemistry analyzer (software Ver. 04-01 or later)

NOTE
- The specifications and equipment requirements can be found in the operator's manual for the abovementioned Nihon Kohden in vitro diagnostic devices.
- Read the SDS (Safety Data Sheet) carefully before use. The SDS is available from your Nihon Kohden representative.
- The SSP (Summary of Safety and Performance) for the D-dimer Control can be obtained from the following URL:
  https://ec.europa.eu/tools/eudamed

0614-908218

Materials Provided and Materials Required

Materials Provided

DD-QC D-dimer Control (Three vials of lyophilised control are supplied in each pack.)

Materials Required (Not Provided with the Reagent)

- DD-421W Celltac chemi D-dimer

Intended Users

This device is intended for professional use only.

Symbols

The following symbols are used with this control. The descriptions of each symbol are given in the table below.

Symbols	Description
	Caution
	Use by
LOT	Lot number
REF	Catalogue number
	Manufacturer
	Operator's manual; operating instructions
#	Model number
UDI	Unique device identifier
IVD	In vitro diagnostic medical device
	Biological risks
CONTROL	Control
	Vial
	Temperature limits
	Keep away from sunlight

Symbols	Description
	This way up
	Fragile
	Keep away from rain
n	Stacking limit by number ("n" is the limiting number)
EC REP	Authorized representative in the European Community/ European Union
CE XXXX	The CE mark is a protected conformity mark of the European Union. The four digits after the CE mark indicate the identification number of the Notified Body involved in assessing the product's conformity as a medical device.

Safety Information

⚠ **WARNING** A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.

Pay attention to all safety information in this operator's manual.

⚠ WARNING
Do not swallow the control. It may be infectious.

⚠ WARNING
When handling the control, wear rubber gloves to protect yourself from infection.

⚠ WARNING
POTENTIALLY BIOHAZARDOUS MATERIAL. This control is potential biohazardous material. The control is intended solely for in vitro diagnostic use by trained personnel. The control contains human-sourced and/or potentially infectious components. Components from human donors used in preparation of the control were tested for the presence of the antibodies to human immunodeficiency virus (HIV-1/HIV-2) and Hepatitis C virus (HCV) as well as for Hepatitis B virus surface antigen and found to be negative. Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

- Do not use the control after the expiration date.
- If microorganisms get into the control or the control vial is turbid, discard the control.
- The calibration cannot be performed on this control.
- Store the control in a pharmaceutical refrigerator.
- Allow the control to warm to temperatures between 15 and 30°C (59 and 86°F) before use.
- Invert and mix the control before use.

Using the Control

Reagents Used

Use the D-dimer Control in combination with a DD-421W Celltac chemi D-dimer.

Frequency of Performing Quality Control

Determine according to inspections performed by each laboratory.

Measurement Principle

Refer to the analyzer operator's manual.

Procedure

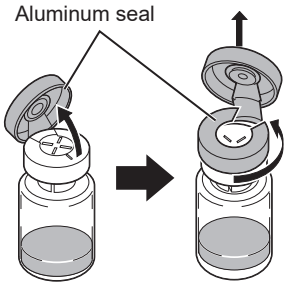
NOTE
- Turbidity, discoloration of the control or unacceptable results may indicate deterioration. Do not use the control if deterioration is suspected.
- Confirm that the lot number of the control matches the lot number on the quality control data label.
- Use the control within the expiration date and dispose of it after the expiration date for disposal of infectious medical waste.
- Invert and mix the control before use.
- Do not mix the control with another control with a different lot or another reagent.
- Do not add the reagent to the control vial.
- If there are unused vial, restore the control at temperatures between 2 and 8°C (36 and 46°F)

Registering the Lot of the Control

1. Take the control out of the refrigerator.
2. Enter the quality control data printed on the package of the control into the analyzer and perform the lot registration.

Measuring the Control

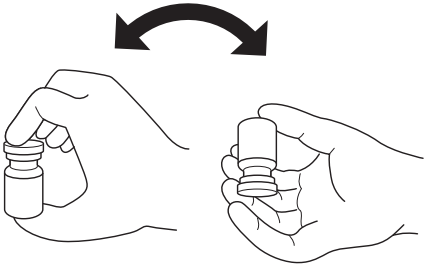
1. Open the control.
   1) Remove the aluminum seal from the vial as follows.



   2) Remove the rubber cap from the vial to open the control.
2. Use the barcode reader provided with the analyzer to scan the barcode on the DD-QC vial. The confirmation window to start the preparation is displayed.
3. Follow the instructions on the analyzer screen to dispense the dilution into the control vial.

   NOTE: When dispensing the dilution, insert the sampling nozzle so that it touches the top of the side wall of the control vial.
4. To ensure thorough mixing of the reagents in the DD-QC, gently invert the control while holding the rubber cap.

   NOTE • Mix the control by gently inverting it to avoid foaming.
   • After mixing, make sure that there are no solids left in the vial.



5. Aspirate the control into the analyzer.

   NOTE: Touching the end of the sampling nozzle against the bottom of the vial obstructs the opening for aspiration, and may prevent aspiration. Leave a slight gap between the end of the sampling nozzle and the bottom of the vial during aspiration of the sample.
6. Close the rubber cap.

   NOTE: If aspirating the control into the analyzer again, invert and mix with the rubber cap closed.

Technical Information

Metrological Traceability of Values Assigned to the Control

D-dimer Calibrator consists of high molecular weight fraction of human cross-linked fibrin degradation products obtained by plasmin fibrinolysis.
Since there is no recognized certified reference material or reference measurement procedure for D-dimer defined in ISO 17511, the traceability of the calibration will be established to a working calibrator prepared.

Values of D-dimer in the reference material are determined using UV spectrophotometry,and and the D-dimer value using Celltac chemi D-dimer is calculated according to traceability of the calibration for this system.

Sterilization Method

D-dimer Control is not intended to be sterilized or kept in a sterile environment.

Composition

D-dimer Control is a lyophilized reagent composed of human plasma.

Storage and Transport Environment

2 to 8°C (36 to 46°F)

NOTE: Do not freeze the dissolved control.

Expiration Date

Shown on the vial or package.

Shelf Life Date After Opening the Package

Once reconstituted, use within 28 days while stored at 2 to 8°C.

Package and Catalog Number

Model	Qty	Catalog Number
DD-QC	3 vials	DD-QC

Disposal

⚠ WARNING

Dispose of the control according to your local laws and your facility's guidelines (including incineration, melt treatment, sterilization, disinfection and request for waste disposal) for disposing of infectious medical waste. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, it may cause infection.

When disposing of the control, such as when the expiration date is past, follow the instructions on the SDS of the control.

Revision History

Edition	Date	Details	Code Number
1st Edition	30 Jul 2025	Initial issue	0614-908218

NOTE: Changes made in the most recent edition are indicated by a bar in the left margin of each page.

Note for users in the territory of the EEA and Switzerland:
Any serious incident that has occurred in relation to the device must be reported to the European Representative designated by the manufacturer and the Competent Authority of the Member State of the EEA and Switzerland in which the user and/or patient is established.

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