

D-dimer Calibrator

DD-CAL

General

Intended Purpose

For in vitro diagnostic use only.

D-dimer Calibrator is calibrator product designed and assigned value to calibrate D-dimer assay of Nihon Kohden clinical chemistry analyzers. This device is intended for use in conjunction with the Celltac chemi D-dimer only and be used for routine maintenance and repair of assay system by service person and laboratory professionals.

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 Calibrator can be obtained from the following URL:
<https://ec.europa.eu/tools/eudamed>

Materials Provided and Materials Required

Materials Provided

DD-CAL D-dimer Calibrator (Three vials of lyophilised calibrator are supplied in each pack.)

0614-908217

Materials Required (Not Provided with the Reagent)

- DD-421W Celltac chemi D-dimer
- Distilled water
- Micro-pipette that can aspirate 0.5 mL of fluid (locally purchased)

Intended Users


This device is used for routine maintenance and repair of assay system by service person and laboratory professionals.

Symbols

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

Symbols	Description	Symbols	Description
	Caution		This way up
	Use by		Fragile
	Lot number		Keep away from rain
	Catalogue number		Stacking limit by number ("n" is the limiting number)
	Manufacturer		Authorized representative in the European Community/ European Union
	Operator's manual; operating instructions		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.
	Model number		
	Unique device identifier		
	In vitro diagnostic medical device		
	Biological risks		
	Calibrator		
	Vial		
	Temperature limits		
	Keep away from sunlight		

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 calibrator. It may be infectious.

 **WARNING**

When handling the calibrator, wear rubber gloves to protect yourself from infection.

 **WARNING**

POTENTIALLY BIOHAZARDOUS MATERIAL. This calibrator is potential biohazardous material. The calibrator is intended solely for in vitro diagnostic use by trained personnel. The calibrator contains human-sourced and/or potentially infectious components. Components from human donors used in preparation of the calibrator 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 calibrator after the expiration date.
- If microorganisms get into the calibrator or the calibrator vial is turbid, discard the calibrator.
- The quality control program cannot be performed on this calibrator.
- Store the calibrator in a pharmaceutical refrigerator.

- Allow the calibrator to warm to temperatures between 15 and 30°C (59 and 86°F) before use.
- Invert and mix the calibrator before use.
- The assay value may vary for each vial. Check the value after every measurement and enter it on the analyzer.

Using the Calibrator

Perform calibration in the following cases.

- Calibration is required as a result of regular quality control.
- Calibration is required as a result of quality control performed after maintenance.
- Other cases where calibration is required.

Reagents Used

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

Frequency of Performing Calibration

Determine according to inspections performed by each laboratory.

Measurement Principle

Refer to the analyzer operator's manual.

Procedure

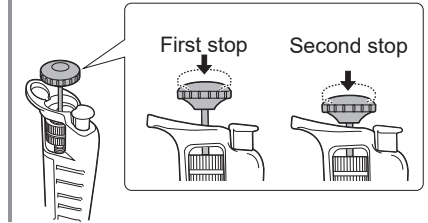
- NOTE**
- Turbidity, discoloration of the calibrator or unacceptable results may indicate deterioration. Do not use the calibrator if deterioration is suspected.
 - Confirm that the lot number of the calibrator matches the lot number on the calibration data label.
 - Use the calibrator within the expiration date and dispose of it after the expiration date for disposal of infectious medical waste.
 - When performing the calibration five times, be careful not to take too much time and avoid performing calibration under significant temperature change.
 - Invert and mix the calibrator before use.

- Do not mix the calibrator with another calibrator with a different lot or another reagent.
- Do not reuse the calibrator. Do not add the reagent to the calibrator vial.
- If there are unused vial, restore the calibrator at temperatures between 2 and 8°C (36 and 46°F)
- Use a new calibrator when calibrating more than one analyzer or when the calibrator runs out before calibration is finished.
- The detail procedure requirements can be found in the calibration section in operator's manual for the abovementioned Nihon Kohden in vitro diagnostic devices.

- 2) Insert the micropipette into the pipette tip to attach it.
- 3) With the micropipette button pressed down to the first stop, insert the tip of the pipette below the liquid level.

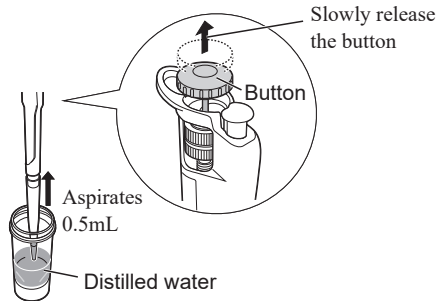


The button can be pressed in two stages.

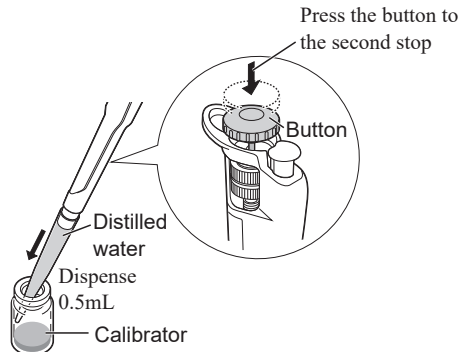


- 4) Slowly release the button to aspirate the distilled water.

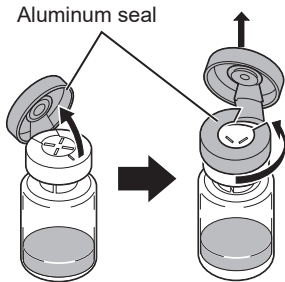
NOTE: To aspirate the specified amount of distilled water, do not allow air bubbles to enter. If air bubbles enter the pipette tip, replace the tip.



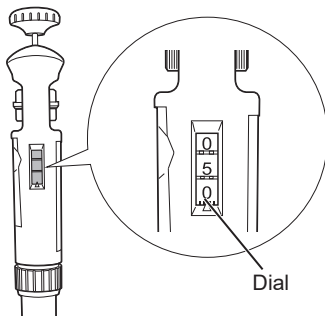
- 5) Press the button to the second stop and dispense the distilled water into the calibrator vial.



1. Take the calibrator out of the refrigerator.
2. Open the lid of the calibrator vial.
 - 1) Remove the aluminum seal from the vial as follows.



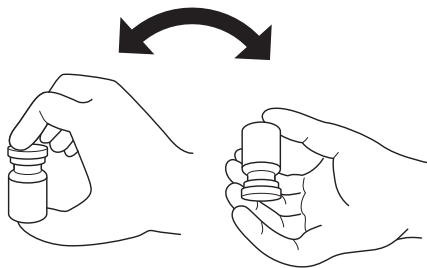
- 2) Remove the rubber cap from the vial to open the calibrator.
3. Dissolve the calibrator.
 - 1) Turn the micropipette dial to 0.5 mL ("050" in the figure below).



4. Enter “Assay value” to the analyzer, refer to calibration data label in the package.
5. To ensure thorough mixing of the reagents in the DD-CAL, gently invert the calibrator while holding the rubber cap.

NOTE

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



6. Aspirate the calibrator 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.

7. Close the rubber cap.

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

Technical Information

Metrological Traceability of Values Assigned to the Calibrator

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 the D-dimer value using Celltac chemi D-dimer is calculated according to traceability of the calibration for this system.

Sterilization Method

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

Composition

D-dimer Calibrator is a lyophilized reagent composed of human serum.

Storage and Transport Environment

2 to 8°C (36 to 46°F)

NOTE: Do not freeze after dissolved.

Expiration Date

Shown on the vial or package.

Shelf Life Date After Opening the Package

Calibrator should be used within the same day it is dissolved.

Once dissolved, use within the day while stored at 2 to 8°C.

Package and Catalog Number

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

Disposal

WARNING

Dispose of the calibrator 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 calibrator, such as when the expiration date is past, follow the instructions on the SDS of the calibrator.

Revision History

Edition	Date	Details	Code Number
1st Edition	30 Jul 2025	Initial issue	0614-908217

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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