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Thermo Fisher Scientific
Thermo Fisher Scientific Oy
Ratastie 2, FI-01620 Vantaa, Finland
thermofisher.com

17.04.2024

URGENT FIELD SAFETY NOTICE

ACTION REQUIRED

Thermo Fisher Scientific D-Dimer Calibration Set

QARA-INFO-43 Rev 01

Dear Valued Customer,

The purpose of this letter is to advise you that Thermo Fisher Scientific Oy, part of Thermo Fisher Scientific Inc., is conducting a Field Safety Corrective Action (FSCA) for the in-vitro diagnostic products listed below (Table 1). Our records indicate that you have purchased units of the affected product. Please read the following information carefully.

Table 1: List of Products.

Product Name	Catalog Number	Lot Number	Expiration Date (DD.MM.YYYY)	UDI
D-Dimer Calibration Set	981871	W717A W717B	30.11.2024 30.11.2024	(01)16438153000751(17)241130(10)W717A (01)16438153000751(17)241130(10)W717B

Intended use:

D-Dimer Calibration Set is used as a calibration set for quantification of D-Dimer in plasma by immunoturbidimetry on Thermo Scientific™ Konelab™ and Indiko™ Clinical Chemistry Analyzers using methods defined by Thermo Fisher Scientific Oy.

Any reference to the Konelab systems also refers to the T Series.

REASON FOR FIELD ACTION

Thermo Fisher Scientific Oy is conducting a field safety corrective action for the product D-Dimer Calibration Set lot W717A and W717B (later W717) due to erroneously low calibrator values.

DESCRIPTION OF THE ISSUE

It has been discovered in an internal investigation that the D-Dimer Calibration Set lot W717 has been assigned calibrator values that are erroneously low. Using lot W717 for calibration of the D-Dimer method may lead in incorrect D-Dimer method calibration on Indiko and Konelab analyzers, leading to falsely decreased D-Dimer results when analyzing patient samples with this calibration. Based on our investigation, values may be falsely decreased by up to 20 %.

Due to the erroneously low calibrator values, lot W717 should not be used for calibration, and patient samples should not be analyzed using lot W717 for calibration.

The issue pertains to D-Dimer Calibration Set lot W717, and no other D-Dimer Calibration Set lots are affected.

RISK TO HEALTH / IMPACT ON PATIENT RESULTS

The use of the affected calibration set lot for D-Dimer method calibration and analyzing patient samples with this calibration poses a risk of producing falsely decreased patient results. The risk to health due to a falsely decreased D-Dimer plasma result is considered low. A falsely decreased D-Dimer result may lead to missing or delayed diagnosis of thromboembolic diseases or an underestimation of the severity of a pulmonary embolism.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings. D-Dimer should not be used alone for diagnosis.

There is no reason to question patient sample results when the D-Dimer method has been calibrated with other D-Dimer Calibration Set lots.

To date no incidents or injuries to patients have been reported.

ACTIONS BEING TAKEN BY THE MANUFACTURER

1. Thermo Fisher Scientific Oy is investigating the cause of this issue.
2. We will provide free of charge replacements for discarded products within the scope of this FSCA.
3. When a new D-Dimer Calibration Set lot is available, we will make available the updated D-Dimer Control (catalog number 981868) and D-Dimer Control High (catalog number 981869) value sheets in e-labeling at https://eifu.thermofisher.com/TSF. The expected availability of the new D-Dimer Calibration Set lot is June 2024.
4. We will take the necessary actions to prevent the reoccurrence of this issue.
5. Thermo Fisher Scientific Oy has informed the appropriate Regulatory Agencies including in the European Union and United Kingdom of this field safety corrective action.

ACTIONS TO BE TAKEN BY A USER

1. Please be aware that the above mentioned (Table 1) Thermo Fisher Scientific products are affected.
2. As appropriate, contact your Medical Professional for evaluation of further action.
3. Please stop using the affected D-Dimer Calibration Set lot W717 and discard the remaining stock of the affected D-Dimer Calibration Set lot.
4. Please contact your Thermo Fisher Scientific representative for free of charge replacement discarded products within the scope of this Field Safety Corrective Action through your normal ordering channel.
5. Once you have received the D-Dimer Calibration Set replacement lot:
    a. Please recalibrate the D-Dimer method utilizing the new lot.
    b. Please upload the updated value sheets for D-Dimer Control (catalog number 981868) and D-Dimer Control High (catalog number 981869) using this link: https://eifu.thermofisher.com/TSF. Insert new control values on your analyzer utilizing these value sheets.
6. Please contact your local Thermo Fisher Scientific representative for further information, if needed.
7. Retain a copy of this letter for your laboratory records if appropriate.

8. Fill out the RESPONSE FORM and return it within 5 days of the date of the letter to your Thermo Fisher Scientific representative as instructed in the form.

ACTIONS TO BE TAKEN BY A DISTRIBUTOR

1. Please notify your customers of this Field Safety Corrective Action using this Field Safety Notice and request they return a response to your contact information. Any adverse events noted on the response must be reported to Thermo Fisher Scientific Oy product support immediately: system.support.fi@thermofisher.com.
2. Fill out the RESPONSE FORM and return it within 10 days of the date of the letter to vigilance.clinical.fi@thermofisher.com.
3. In case you or your customers have affected product in stock, please contact Thermo Fisher Scientific Oy product support at system.support.fi@thermofisher.com with "QARA-INFO-43" on email subject line for information on replacement products.
4. Please note that once the replacement lot is available, updated D-Dimer Control (catalog number 981868) and D-Dimer Control High (catalog number 981869) value sheets are available on e-labeling at https://eifu.thermofisher.com/TSF The expected availability of the new D-Dimer Calibration Set lot is June 2024.
5. Please maintain records of all Field Safety Corrective Actions and response forms. If necessary, such as a request from a Regulatory Agency, we will request copies of these records to be provided to us.
6. For distributors outside the European Union, it is your obligation to notify your local Regulatory Agency of this Field Safety Corrective Action according to your local regulations.

We appreciate your immediate attention to this field safety notice. Please distribute this information immediately to any staff that may be impacted by this issue. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

Sincerely,

Electronically signed by: Rina Wahlroos
Reason: Approver of the GxP document
Date: Apr 17, 2024 12:31 GMT+3

Rina Wahlroos

Director, Quality Assurance and Regulatory Compliance
Thermo Fisher Scientific Oy
Biomarkers, Automation & Instrumentation
Clinical Diagnostics Division