Thermo Fisher Scientific
Thermo Fisher Scientific Oy
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thermofisher.com

05.06.2024

URGENT FIELD SAFETY NOTICE

ACTION REQUIRED

Thermo Fisher Scientific 981813 Cholesterol

QARA-INFO-44 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
Cholesterol	981813	WB28 WA26	31.03.2025 31.03.2025	(01)16438153818134(17)250331(10)WB28 (01)16438153818134(17)250331(10)WA26

Intended use:

For *in vitro* diagnostic use in the quantitative determination of cholesterol concentration in human serum or plasma on Thermo Scientific™ Indiko™ and Konelab™ analyzers.
Any reference to the Konelab systems also refers to the T Series.

REASON FOR FIELD ACTION

It has been identified that the response level for Cholesterol (catalog number 981813) lot WB28 and WA26 has been reduced. The decreased response level has resulted in decreased linearity and creates a risk of falsely decreased patient results.

DESCRIPTION OF THE ISSUE

Thermo Fisher Scientific Oy has become aware through customer complaint investigation that the Cholesterol reagent lots WB28 and WA26 response levels have decreased over time. This has resulted in decreased linearity at the high end (10 – 15 mmol/l) of Cholesterol measuring range. The reduced linearity may cause up to a 15% decrease in reported cholesterol results for patient samples within this concentration range. The issue is linked to a specific raw material lot used in the manufacturing of the impacted Cholesterol product lots. There is no reason to question the performance of other Cholesterol lots.

The affected Cholesterol reagent lots should not be used for patient sample analysis on Indiko and Konelab analyzers and should be discarded.

The issue may result in “Factor limit max” error being triggered on Indiko analyzer during calibration. Simultaneous to this error message, calibration automatic acceptance is changed to manual acceptance. Calibration should not be approved if errors have occurred. Please note that factor limits are not applicable for the Konelab cholesterol method.

RISK TO HEALTH / IMPACT ON PATIENT RESULTS

The decreased linearity may lead to falsely decreased patient results at the high end of the primary measuring range. The risk to health due to a falsely decreased cholesterol result is considered low.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination, and other findings.

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. We will take the necessary actions to prevent the reoccurrence of this issue.
4. Thermo Fisher Scientific Oy has informed the appropriate Regulatory Agencies including in the European Union, Norway, Switzerland 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 Cholesterol lots WB28 and WA26 and discard the remaining stock of the affected Cholesterol lot.
4. Please contact your Thermo Fisher Scientific representative for free of charge replacement of discarded products within the scope of this Field Safety Corrective Action through your normal ordering channel.
5. Retain a copy of this letter for your laboratory records if appropriate.
6. 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.
7. Please contact your local Thermo Fisher Scientific representative for further information, if needed.

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. Please discard the remaining stock of the affected Cholesterol lots.
4. 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-44” on email subject line for information on replacement products.

5. Please maintain records of all Field Safety Corrective Actions and customer 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 cause 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: Jun 5, 2024 09:55 GMT+3

Rina Wahlroos

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