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

03.01.2024

FIELD SAFETY NOTICE
ACTION REQUIRED
Thermo Fisher Scientific 981954 Urea
QARA-INFO-42 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(s). Please read the following information carefully.

Table 1: List of Products.

Product Name	Catalog Number	Lot Number	Expiration Date (DD.MM.YYYY)	UDI
Urea	981954	W341	31.01.2025	(01)16438153007361(17)250131(10)W341
		W407	31.01.2025	(01)16438153007361(17)250131(10)W407
		W514	31.03.2025	(01)16438153007361(17)250331(10)W514
		W546	31.03.2025	(01)16438153007361(17)250331(10)W546
		W739	30.04.2025	(01)16438153007361(17)250430(10)W739
		W831	30.04.2025	(01)16438153007361(17)250430(10)W831
		W955	30.06.2025	(01)16438153007361(17)250630(10)W955
		W921	30.06.2025	(01)16438153007361(17)250630(10)W921

Intended use:

For *in vitro* diagnostic use in the quantitative determination of urea concentration in human serum, plasma or urine 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 absorbance level of certain Urea product lots decreases over time. The decreased absorbance may result in reduced linearity and create a risk of falsely decreased results.

DESCRIPTION OF THE ISSUE

Thermo Fisher Scientific Oy has discovered through internal investigation that the absorbance level of certain Urea lots (see Table 1) decreases over time. The decreased absorbance may result in reduced linearity at the high end of Urea measuring range. Reduced linearity may result in a falsely decreased result. The issue is linked to a specific raw material lot used in the manufacturing of the

impacted Urea product lots. There is no reason to question the performance of other Urea product lots.

If the absorbance falls below the predetermined limit, the sample result is flagged with “Init abs. low” error message. In some cases, an additional “Linearity” error message may also be displayed. Simultaneous to these error messages, result automatic acceptance is changed to manual acceptance.

Patient sample results with the “Init abs. low” or “Init abs. low” and “Linearity” error messages should not be reported as the results may be falsely decreased. Quality control results should not be accepted if errors have occurred. If the quality control results are not acceptable, patient samples should not be analyzed. If no errors have occurred, there is no reason to question the patient sample or quality control results.

RISK TO HEALTH / IMPACT ON PATIENT RESULTS

The decreased absorbance may result in reduced linearity and create a risk of falsely decreased patient results. The risk to health due to a falsely decreased serum or plasma urea result is considered low. A falsely decreased urine urea result is not expected to lead to risk to health.

There is no reason to question the patient sample or quality control results when no error messages have been displayed.

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 error.
2. We will provide free of charge replacement for any discarded products within the scope of the 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, United Kingdom and Canada 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. You may use the impacted products until a replacement lot is available as follows:
    a. In case no error messages are displayed, the Urea product can be safely used until you have received the replacement lot.
    b. In case you get an error message “Init abs. low” or “Init abs. low” and “Linearity” combined for the impacted lots, do not use the test result and do not report it out. Please discard the remaining stock of the affected product.
3. Please contact your Thermo Fisher Scientific representative for free of charge replacement for any discarded product within the scope of the Field Safety Corrective Action through your normal ordering channel.
4. As appropriate, contact your Medical Professional for evaluation of further action.
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.

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 kits in stock, please contact Thermo Fisher Scientific Oy product support at system.support.fi@thermofisher.com with "QARA-INFO-42" on email subject line for information on replacement products.
4. 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.
5. 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,

Rina Wahlroos

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

FIELD SAFETY NOTICE RESPONSE FORM
Thermo Fisher Scientific 981954 Urea
QARA-INFO-42

☐ I confirm I have read, understand, and taken action according to the attached Medical Device Field Safety Notice instructions.

☐ I understand that this applies to the medical device listed in Table 1 that I have received.

Product Name	Catalog Number	Lot Number	Expiration Date (DD.MM.YYYY)	UDI
Urea	981954	W341	31.01.2025	(01)16438153007361(17)250131(10)W341
		W407	31.01.2025	(01)16438153007361(17)250131(10)W407
		W514	31.03.2025	(01)16438153007361(17)250331(10)W514
		W546	31.03.2025	(01)16438153007361(17)250331(10)W546
		W739	30.04.2025	(01)16438153007361(17)250430(10)W739
		W831	30.04.2025	(01)16438153007361(17)250430(10)W831
		W955	30.06.2025	(01)16438153007361(17)250630(10)W955
		W921	30.06.2025	(01)16438153007361(17)250630(10)W921

Do you have any knowledge of adverse medical events associated with the products listed in this Medical Device Field Safety Notice?

☐ Yes ☐ No

If yes, please explain: _____

and Contact: system.support.fi@thermofisher.com

For Distributors Only:

☐ We have identified and notified my customers that were delivered this product. We will monitor and ensure customers have taken action.

Notification to local Regulatory Agency:

☐ We have notified our local authority and will provide report to vigilance.clinical.fi@thermofisher.com if requested.

☐ We are not required to report to our local authority.

PLEASE RETURN COMPLETED AND SIGNED FORM TO EMAIL WITHIN 10 DAYS UPON RECEIPT: vigilance.clinical.fi@thermofisher.com

Name/Title:	
Date:	
Company/Institute:	
Phone:	
Email:	
Signature:	

It is important that your organization takes action as detailed in this letter and also replies without delay by using this response form. Your reply is evidence, which Thermo Fisher Scientific and Regulatory Authorities need to monitor the progress.

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Distributors, this response template is being provided for your convenience. Please place this letter on to your own letterhead and collect responses from your customers. Please note, customers should provide their response directly to your contact information.

FIELD SAFETY NOTICE RESPONSE FORM
Thermo Fisher Scientific 981954 Urea
QARA-INFO-42

☐ I confirm I have read, understand, and taken action according to the attached Medical Device Field Safety Notice instructions.

☐ I understand that this applies to the medical device listed in Table 1 that I have received.

Product Name	Catalog Number	Lot Number	Expiration Date (DD.MM.YYYY)	UDI
Urea	981954	W341	31.01.2025	(01)16438153007361(17)250131(10)W341
		W407	31.01.2025	(01)16438153007361(17)250131(10)W407
		W514	31.03.2025	(01)16438153007361(17)250331(10)W514
		W546	31.03.2025	(01)16438153007361(17)250331(10)W546
		W739	30.04.2025	(01)16438153007361(17)250430(10)W739
		W831	30.04.2025	(01)16438153007361(17)250430(10)W831
		W955	30.06.2025	(01)16438153007361(17)250630(10)W955
		W921	30.06.2025	(01)16438153007361(17)250630(10)W921

Do you have any knowledge of adverse medical events associated with the products listed in this Medical Device Recall/Field Safety Notice?

☐ Yes ☐ No

If yes, please explain: _____

and Contact: ***Distributors, please add your contact information here.***

PLEASE RETURN COMPLETED AND SIGNED FORM TO EMAIL WITHIN 5 DAYS UPON RECEIPT: ***Distributors, please add your contact information here.***

Name/Title:	
Date:	
Company/Institute:	
Phone:	
Email:	
Fax: (Optional)	
Signature:	

It is important that your organization takes action as detailed in this letter and also replies without delay by using this response form. Your reply is evidence, which Thermo Fisher Scientific and Regulatory Authorities need to monitor the progress.