FIELD SAFETY NOTICE
ACTION REQUIRED

Thermo Fisher Scientific 981952 Bilirubin Total (DCA)
Decreased linearity range

01.06.2023

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 for the in vitro diagnostic products listed below (Table 1.). Our records indicate that you have purchased units of the affected products.

REASON FOR FIELD CORRECTION:

It has been identified that the Bilirubin Total (DCA) assay linearity is decreased at the high end of the primary measuring range. The decreased linearity creates a risk of falsely decreased patient results.

Table 1. Product information

Product Name	Product code	Lot	Expiry Date
Bilirubin Total (DCA)	981952	V781	2023-06
		VA38	2023-07
		VB94	2023-09
		W154	2023-12
		W267	2023-12

Total Bilirubin (DCA) is intended for in vitro diagnostic use in the quantitative determination of total bilirubin in human serum or plasma on Thermo Scientific™ Indiko™ and Konelab™.

DESCRIPTION OF THE ISSUE

Thermo Fisher Scientific Oy has discovered through internal investigation that the linearity of the Bilirubin Total (DCA) assay (Product Code 981952) is reduced at the high end (450 – 500 µmol/L) of the total bilirubin primary measuring range. The reduced linearity may cause a decrease in reported total bilirubin results for patient samples with total bilirubin concentrations in this range. As an outcome of this finding, the test dilution limit for the assay is being lowered from the current 500 µmol/L to 400 µmol/L to ensure measurement of undiluted samples within the linear range.

As part of this investigation, it was additionally identified that the instructions for use for the Bilirubin Total (DCA) assay were not sufficiently clear that the intended use of the product is limited to adult human serum and plasma samples. In response to that observation, the instructions for use for the Bilirubin Total (DCA) assay is being updated to further clarify that the performance of the assay has not been validated with neonatal specimens.

IMPACT ON PATIENT RESULTS

The risk for adult patient harm due to a falsely decreased total bilirubin result at the 450 – 500 µmol/L concentration level is considered low as a slight decrease in the reported total bilirubin value at this level is anticipated not to impact the patient treatment decision.

Total bilirubin expected values for healthy adults are 2 – 21 µmol/L (0.1 – 1.2 mg/dL)[1] and the expected values should serve as guidance only. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings and an unexpected test result should be repeated according to the laboratory's policies.

Where the assay has previously been used erroneously for evaluation of neonate patient samples, there is a low risk for serious injury. Reporting a lower than accurate bilirubin level could delay access to appropriate treatment, as providing a result for total bilirubin that is lower than the actual value has the potential to negatively impact clinical decisions.

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

[1] Thomas L (ed.), Clinical Laboratory Diagnostics; Use and Assessment of Clinical Laboratory Results, 1st edition, TH-Books Verlagsgesellschaft mbH, Frankfurt/Main, Germany, pp. 192 - 202, 1998.

ACTIONS TO BE TAKEN BY THE CUSTOMER / USER:

1. Please be aware that the above mentioned (Table 1) Thermo Fisher Scientific product is affected.
2. Please update your analyzer software to adjust the test dilution limit per the updated application notes attached to this letter.
3. As appropriate, contact your Medical Professional for evaluation of further action.
4. Retain a copy of this letter for your laboratory records.
5. Please contact your local Thermo Fisher Scientific representative for further information, if needed.
6. Fill out the RESPONSE FORM and return it within 5 days of the date of the letter to your distributor as instructed in the form.

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR/SALES OFFICE:

Please contact your affected customer base, advise them of the situation, and provide them with a copy of this letter that we have provided for your convenience. Any adverse events noted on the response forms must be reported to Thermo Fisher Scientific Oy product support immediately: system.support.fi@thermofisher.com.

Please, fill out the MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM and return it within 10 days to Thermo Fisher Scientific as instructed in the form. Distributors outside European Union (EU) are required to act according to local regulatory requirements and if required inform local regulatory authorities. Please note that you are also required to inform Thermo Fisher Scientific if authority reporting is required and when it has been completed and closed by your local authority, when appropriate.

ACTIONS TAKEN BY THE MANUFACTURER:

1. The Indiko™ and Konelab™ application notes have been updated to lower the application dilution limit from 500 µmol/L (29 mg/dL) to 400 µmol/L (23 mg/dL) and will be released in June 2023.
2. The primary measuring range upper limit has been updated from 500 µmol/L (29 mg/dL) to 400 µmol/L (23 mg/dL) in the Bilirubin Total (DCA) instructions for use. Note that the extended measuring range is not impacted.
3. The instructions for use have been updated to advise the performance of the assay has not been validated with neonatal specimens and is intended for use only with adult human samples.
4. The updated application notes are attached to this letter and made available on ShowPad platform (http://thermofisherscientific.showpad.biz). The updated instructions for use are available on http://edfu.thermofisher.com.

Thermo Fisher Scientific Oy has informed the appropriate Regulatory Agencies in the European Union, Norway, Switzerland, United Kingdom and Canada of this field safety corrective action.

We appreciate your immediate attention to this Field Safety Notice. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

If you have any further questions, please contact your local Thermo Fisher Scientific representative or send an email to system.support.fi@thermofisher.com.

Sincerely,

Electronically signed by: Rina Wahlroos
Reason: Approver of the GxP document
Date: Jun 1, 2023 14:39 GMT+3

Rina Wahlroos
Director, Quality Assurance & Regulatory Compliance
Thermo Fisher Scientific Oy
Analyzers & Automation
Clinical Diagnostics

MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM

Thermo Fisher Scientific 981952 Bilirubin Total (DCA)
Decreased linearity

It is important that your organisation 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 of Field Safety Correction. Without your reply Thermo Fisher Scientific Oy cannot verify the effectiveness or completeness of this Field Safety Correction.

Customer/Distributor - Contact details:	
Company name:	
Name and title:	
Company address:	
Telephone:	
Email:	
Customer/Distributor - Please fill in as appropriate:	
☐	I have read and understood the attached Field Safety Notice and field action instructions.
☐	I understand that this applies to all inventory of the affected in vitro diagnostic medical device products, listed in Table 1, that I have received.
Do you have any knowledge of adverse medical events associated with the products listed in this Field Safety Notice? ☐ No ☐ Yes (please describe below) _____ _____ _____	
Distributor – Please fill in as appropriate: ☐ Not appicable	
☐	I have identified and notified my customers that were shipped or may have been shipped products affected by this Field Safety Action.
Please specify the date and method of notification: _____ _____	

☐ Yes ☐ No	For distibutors outside EU: Is a local authority notification required?

If you have selected Yes, please note that you are expected to complete the notification and inform vigilance.clinical.fi@thermofisher.com when the notification has been closed by your local authority.

Customer/Distributor - Signature:

Date:	
Signature:	
Name:	

Customers: Please return completed and signed form to your distributor within 5 days of receipt.

Distributors: Please return completed and signed form by email to: vigilance.clinical.fi@thermofisher.com within 10 days of receipt.