September 23, 2020

FIELD SAFETY NOTICE
ACTION REQUIRED

Erroneous results for Direct Bilirubin, Bilirubin Total (NBD), Creatinine (Jaffe), and Creatinine (Enzymatic) assay results due to interference by Eltrombopag and additional interference with Creatinine (Enzymatic) assay results by Phenindione

Dear Valued Distributor:

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 as 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 patients treated with Eltrombopag or Phenindione may receive incorrect test results as defined above. No incidents, injuries or incorrect patient results have been reported.

The information related to Phenindione and Eltrombopag interferences provided in this letter serves as interim instructions until the current Instructions For Use is updated.

Table 1. PRODUCT INFORMATION

Product Name	Product Code	Lot No.	Impact on test results
Bilirubin Direct	981909 981892	All lots	Patients treated with **Eltrombopag**, may receive falsely low/high results
Bilirubin Total (NBD)	981793 981897	All lots	Patients treated with **Eltrombopag**, may receive falsely low/high results
Creatinine (Jaffe)	981810 981811	All lots	Patients treated with **Eltrombopag**, may receive falsely low/high results
Creatinine (Enzymatic)	981845 981896	All lots	Patients treated with **Eltrombopag**, may receive falsely low/high results
Creatinine (Enzymatic)	981845 981896	All lots	Patients treated with **Phenindione**, may receive falsely low results

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Eltrombopag interference

Eltrombopag in an oral thrombopoietin receptor agonist that may be used in the treatment of thrombocytopenia and/or aplastic anemia. It is highly coloured (reddish-brown) and reports show that it can cause serum/plasma discolouration. Interferences appears to be pH dependent and method specific. Eltrombopag is not frequently used as medication due to relatively narrow indication for use and its potential for significant side effects.
Patients treated with **Eltrombopag**, may receive falsely low/high results for the above listed products (see Table 1.).

Phenindione interference

Phenindione is an anticoagulant which functions as a Vitamin K antagonist. It has been identified that patients treated with phenindione may receive falsely decreased creatinine results when using enzymatic creatinine method. Phenindione has serious potential side effects and is used infrequently.
Patients treated with **Phenindione**, may receive falsely low results for the above listed Creatinine (Enzymatic) products (see Table 1.).

IMPACT ON PATIENT RESULTS:

The risk of misdiagnosis and inappropriate therapy exist, especially if results are assessed separately. For diagnostic purposes, the result should always be assessed with the patient's medical history, clinical examination and other diagnostic findings.

According to the information at hand the two medications, Eltrombopag and Phenindione, are infrequently prescribed due to the potential for significant side effects.

ACTIONS TO BE TAKEN BY THE CUSTOMER / USER:

1. If laboratory results of above mentioned tests are inconsistent with clinical observations for patients treated with Eltrombopag, measurements should be repeated using another method. Special attention on choosing the appropriate method for assessing potential drug induced hepatotoxicity is needed as Eltrombopag interferes with Bilirubin assays.
2. Results obtained from patients under Phenindione therapy with Creatinine (enzymatic) assay, should not be used for diagnosis. Measurements should be repeated using another method, e.g. Creatinine Jaffe.
3. Retain a copy of this letter for your laboratory records.
4. As appropriate, contact your Medical Professional for evaluation of further action.
5. Fill out the MEDICAL DEVICE FIELD CORRECTION - 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:

If you are a distributor of the products, please contact your affected customer base, advise them of the situation, and provide them with a copy of the customer letter, that we have provided for your convenience, after you insert your contact information, email and fax numbers in the Customer Letter and Medical Device Field Correction Response Form prior to sending out to your affected customers. 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 CORRECTION - Response Form for distributors and return it within 10 days to Thermo Fisher Scientific as instructed in the form. Distributors outside of the European Union (EU) are required to act according to local regulatory requirements and if required inform local regulatory authorities.

TYPE OF ACTIONS TO BE TAKEN BY THE MANUFACTURER:

Thermo Fisher Scientific Oy has informed the appropriate Regulatory Agencies in the European Union of this field safety corrective action.

We appreciate your immediate attention to this Field Safety Corrective Action. 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,

Rina Wahlroos
Director, Quality Systems and Compliance Affairs
Thermo Fisher Scientific Oy
Analyzers & Automation
Clinical Diagnostics

MEDICAL DEVICE FIELD CORRECTION
Response Form

Erroneous results for Direct Bilirubin, Bilirubin Total (NBD), Creatinine (Jaffe), and Creatinine (Enzymatic) assay results due to interference by Eltrombopag and additional interference with Creatinine (Enzymatic) assay results by Phenindione

I have read and understand the attached Field Safety Notice and field action instructions: _____ (initials)

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: _____ (initials)

Do you have any knowledge of adverse medical events associated with the products listed in this Field Safety Notice?
_____ Yes _____ No

If yes, please explain:

_____

_____

I have identified and notified my customers that were shipped or may have been shipped products affected by this letter by [specify date and method of notification]:

_____

_____

PLEASE RETURN COMPLETED AND SIGNED FORM TO EMAIL:
vigilance.clinical.fi@thermofisher.com

Signature of Acknowledgement and Receipt by Distributor:

_____

Name/Title:	
Date:	
Company:	
Telephone:	
Email Address:	

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 Agencies need to monitor the progress of FSCAs. Without your reply Thermo Fisher Scientific Oy cannot verify the effectiveness or completeness of this Field Safety Corrective Action.