May 22, 2020

FIELD SAFETY NOTICE
ACTION REQUIRED

Rheumatoid Factors 2 (RF 2) test over recovery

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.

Table 1. PRODUCT INFORMATION

Product Name	Product code	Lot No.
Rheumatoid Factors 2 (RF 2)	981920	R113 (Exp. 2020-08-31)
Rheumatoid Factors 2 (RF 2)	981920	R315 (Exp. 2020-08-31)
Rheumatoid Factors 2 (RF 2)	981920	Following already expired lots: MA12 (Exp. 2018-04-30) MC28 (Exp. 2018-04-30) N501 (Exp. 2018-04-30) N771 (Exp. 2018-11-30) N949 (Exp. 2018-11-30) NA90 (Exp. 2018-11-30) P132 (Exp. 2018-11-30) P421 (Exp. 2019-12-31) P932 (Exp. 2019-12-31) P932B (Exp. 2019-12-31)
Rheumatoid Factors Control	981252	Lot S376A, S376B (Exp. 2021-05-31)
Rheumatoid Factors Control	981252	Following already expired lots: MA93A (Exp. 2018-04-30) N149A, N149B, N149C (Exp. 2018-11-30) NC04A, NC04B (Exp. 2019-07-30) PA09A, PA09B (Exp. 2020-01-31)

REASON FOR FIELD CORRECTION:

It has been identified that the RF values for the above-listed lots of Rheumatoid factors 2 (RF2) test (Product Code 981920) calibrator and associated control Rheumatoid Factors Control (Product Code 981252), have been incorrectly assigned, resulting in over recovery of patient test results to the RF reference material 1st British standard from NIBSC Ref 64/002.

Through this communication, customers are being directed to stop using the impacted RF2 lots and begin using replacement material (Product Code 981920 Lot S642B or later), which has been produced to align more closely with the RF reference material, NIBSC Ref 64/ 002. Customers can continue using Rheumatoid Factors Control (Product code 981252) Lot S376 with newly reassigned control values to be in line with the adjusted test level as detailed below.

When first testing with the newly released lot (981920 Rheumatoid Factors 2 Lot S642B) or subsequent lots you may observe a decrease of approximately 23 % in patient results and controls when compared to the most recent lots R113 and R315 of the same product.

IMPACT ON PATIENT RESULTS:

With the continued use of the lots listed in Table 1, there is a risk of reporting incorrect results, falsely elevated levels, which may lead to unnecessary additional serological testing.

ACTIONS TO BE TAKEN BY THE CUSTOMER / USER:

1. If you have inventory of the above mentioned (Table 1) Thermo Fisher Scientific products stop using listed lots of the Rheumatoid Factors (RF2) test (Product Code 981920). You can continue using Rheumatoid Factors Control (Product Code 981252) Lot S376 with newly reassigned control values as detailed below.
2. Retain a copy of this letter for your laboratory records.
3. Please contact your local Thermo Fisher Scientific representative for further information and for replacement RF2 product.
4. As appropriate, contact your Medical Professional for evaluation of further action.
5. If you have inventory please destroy RF2 products according to local waste management rules.
6. 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.

Affected RF2 kits must be destroyed locally according to local waste management rules. Please inform our Customer Care Center of the number of RF2 kits to be credited (kits that you still have in your warehouse or at your customer's site):
customerservice.fi@thermofisher.com

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.

The calibrator value for product code 981920 (from Lot S642B, Exp. 2021-04-30) and control value for product code 981252 (from Lot S376, Exp. 2021-05-31) have been adjusted to the manufacturer's original test level to realign more closely to the reference material 1st British standard from NIBSC Ref = 64/ 002.

NOTE: Updated Rheumatoid Factors Control 981252 lot S376 value sheet is available in e-labeling. Please download your copy from the e-documents using the link and key code given below:

http://www.e-labeling.eu/TSF, key code TSF981252VS_S376

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,

Silja Halme
Director, Quality Assurance & Regulatory Affairs
Thermo Fisher Scientific Oy
Analyzers & Automation
Clinical Diagnostics

MEDICAL DEVICE FIELD CORRECTION
Response Form

Rheumatoid Factors 2 (RF 2) test over recovery

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, and I have destroyed the existing affected RF2 kit inventory (if any): _____ (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 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.