ThermoFisher SCIENTIFIC

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Field Safety Notice
FSN2020-02

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE – IMMEDIATE ACTION REQUIRED
EliA Stool Extraction Kit and EliA Stool Extraction Kit 2

[Insert date]

[Insert Customer or Distributor name
Attn:
Customer / Distributor address]

Dear <insert Customer name or> Thermo Fisher Scientific Dealer Partner:

The purpose of this letter is to advise you that Phadia AB, part of Thermo Fisher Scientific, is issuing a Field Safety Notification for:

Product	Material number	Affected lot number
EliA Stool Extraction Kit	14-5638-01	0236, 0237 and 0238
EliA Stool Extraction Kit 2	14-5651-01	0293, 0295, 0299, 0300, 0301, 0302, 0303, 0304, 0305, 0306, 0307 and 0309

REASON FOR VOLUNTARY RECALL/FIELD SAFETY NOTICE:
One customer complaint has been reported where EliA Stool Extraction Kit 2 had only three instead of four notches on the dipstick rod.

Investigation showed that there could be other error modes such as missing or broken dipstick rods as well as missing notches. If a broken dipstick rod in EliA Stool Extraction Kit or EliA Stool Extraction Kit 2 is used for stool sampling, it may lead to falsely low or negative results.

- 1 missing notch may lead to falsely negative results between 37mg/kg and 50mg/kg.
- 2 missing notches may lead to falsely negative results between 25mg/kg and 50mg/kg.
- 3 missing notches may lead to falsely negative results between 12,5 mg/kg and 50mg/kg.

There have been no reports of adverse events as a result of a broken dip stick rod in the EliA Stool Extraction Kit 2.

RISK TO HEALTH:
In case of falsely low or negative results for fecal calprotectin, the physician may erroneously believe the patient has functional and not inflammatory bowel disease. This could lead to a delayed diagnosis of symptomatic chronic disease. A delay in diagnosis and prolonged suffering from chronic disease may cause reversible injury, however the probability for harm caused by falsely low or negative fecal calprotectin results is remote.

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER OR DISTRIBUTOR:

- Please ensure that the dipstick rod for the affected lots of EliA Stool Extraction Kit or EliA Stool Extraction Kit 2 has four notches before use.

- Please scrap or return any broken dipstick rod and order a replacement product for free of charge.

- Please assess the test results from affected lots of EliA Stool Extraction Kit or EliA Stool Extraction Kit 2 and determine if retesting of samples is needed according to your internal operating procedures. All positive results ≥50 mg/kg can be considered as true positive.

TYPE OF ACTION BY THE MANUFACTURER:

- Corrective and preventive actions (CAPA) have been initiated to prevent this from recurring.

If this letter is being sent to a Distributor, use the following paragraph as well if the Distributor will be conducting the recall in regard to its customers:

Our records indicate that you may have purchased one or more of the above products for re-sale to your customers. You should complete the attached Acknowledgment Form in regard to inventory you have received and/or which is still in stock. In addition, please contact your affected customer base, advise them of the situation, and provide them with a copy of this letter. You should insert your contact information, email and fax numbers in the Acknowledgment Form and request that they return the Acknowledgment Form to you. In addition, qualified product support technicians will be available to address any questions about the affected product at <insert phone number>.

We appreciate your immediate attention to this field correction. By returning the attached Acknowledgment Form you will facilitate our reporting of this matter to the appropriate Regulatory Authorities. 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 questions, please contact <name, department, etc.> at <email address, phone number, fax number, etc.>.

Sincerely,

Name
Title

ThermoFisher SCIENTIFIC

MEDICAL DEVICE FIELD SAFETY NOTICE RETURN RESPONSE

Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION:
[Customer name
Attn:
Address]

EliA Stool Extraction Kit and EliA Stool Extraction Kit 2

I have read and understand the information in the attached FSN2020-02

_____ (initials)

Any adverse events associated with the recalled product? _____ Yes _____ No

If yes, please explain:

_____

AFFECTED PRODUCT INFORMATION [revise as necessary]:

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Use additional sheet(s) if necessary.

RETURN RESPONSE (please provide additional information, if applicable):

PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING EMAIL < > OR FAX NUMBER < >, ATTN: < >

Signature of Receipt by Customer: _____

Name/Title:	
Telephone:	
Email Address:	