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Field Safety Notice
ID: FSN2020-08

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE/RECALL
IMMEDIATE ACTION REQUIRED
EliA dsDNA Well

Date: December 7, 2020

Dear customer:

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:

Product	Material number	Carrier lot number	Kit lot number
EliA dsDNA Well	14-5500-01	BFA3Y	0142

REASON FOR VOLUNTARY RECALL/FIELD SAFETY NOTICE:
Customer complaints have reported a decrease of values for EliA ANA Positive Control when using the EliA dsDNA Well lot BFA3Y/ 0142.

The internal investigation showed the EliA dsDNA Well lot BFA3Y/ 0142 gives higher results, and in some cases the results may be up to 3 times higher than for other EliA dsDNA Well lots.
Results >15 IU/ml to 45 IU/ ml may potentially be false positive.
The investigation has concluded that there are no deviations for the EliA ANA Positive Control or other EliA dsDNA Well lots.

There have been no reports of adverse events as a result of the EliA dsDNA Well lot BFA3Y/ 0142.

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RISK TO HEALTH:

When used to aid in the diagnosis of SLE, falsely elevated or positive results may lead the physician to erroneously believe the patient has SLE when the symptoms are cause by other pathology. This may lead to initiating drug therapy in error. When used for monitoring, falsely elevated results may lead the physician to erroneously believe the patient has more active disease. This may lead to transient inappropriate drug therapy. As a result, in both scenarios the patient may suffer from reversible side effects until the misdiagnosis is identified, e.g. at the next physician's visit and diagnostic workup, however the probability for harm caused by falsely elevated or positive EliA dsDNA results is estimated to be remote.

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER:

- Please scrap or return EliA dsDNA Well lot BFA3Y/ 0142 and order a replacement for free of charge.

- Please assess the test results from EliA dsDNA Well lot BFA3Y/ 0142 and determine if retesting of samples is needed according to your internal operating procedures. Results >15 IU/ml to 45 IU/ml may be potentially false positive.

- Please fill in Acknowledgement Form in the Field Safety Notice, FSN2020-08 and return the response to the contact person as described.

TYPE OF ACTION BY THE MANUFACTURER:

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

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 Thermo Fisher Diagnostics B.V.-ImmunoDiagnostics Division at info-nl.idd@thermofisher.com, Phone no. +31 (0)30 602 37 00.

Sincerely,

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Product Care Manager – Allergy and Autoimmunity
ImmunoDiagnostics

Thermo Fisher Scientific
Thermo Fisher Diagnostics B.V. | Fultonbaan 24, NL-3439 NE Nieuwegein, The Netherlands
Postbus 696, NL-3430 AR Nieuwegein, The Netherlands
Phone +31 (0) 30 602 37 00 | Mobile +31 (0) 6 51 45 50 37
.....@thermofisher.com | www.thermoscientific.com/phadia

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MEDICAL DEVICE FIELD SAFETY NOTICE RETURN RESPONSE

Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION:

Location: _____

Name: _____

EliA dsDNA Well lot BFA3Y/ 0142

I have read and understand the information in the attached FSN2020-08

_____ (initials)

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

If yes, please explain:

_____

AFFECTED PRODUCT INFORMATION:

Product	Material number	Carrier lot number	Kit lot number
EliA dsDNA Well	14-5500-01	BFA3Y	0142

Use additional sheet(s) if necessary.

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

PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING EMAIL:
info-nl.idd@thermofisher.com

Signature of Receipt by Customer: _____

Name/Title:	
Telephone:	
Email Address:	