

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

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
EliA dsDNA Well	14-5500-41	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.

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 caused 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 contact:

Area Manager Jari Siuro (+358 400 304750; jari.siuro@thermofisher.com) or Sales & Application Specialist Hannakaisa Jaatinen (+358 40 769 0290; hannakaisa.jaatinen@thermofisher.com).

We apologize for any inconvenience this may cause.

Sincerely,

Josefina Alander

Sales Manager

ImmunoDiagnostics

Thermo Fisher Scientific

Thermo Fisher Diagnostics Oy

Ratastie 2 | FI-01620 Vantaa, Finland

Mobile +358 50 3090 189 | Phone office +358 10 3292 117 | Fax +358 10 3292 531

josefina.alander@thermofisher.com | www.thermoscientific.com/phadia

MEDICAL DEVICE FIELD SAFETY NOTICE RETURN RESPONSE

**Acknowledgment & Receipt Form
Response Required**

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
EliA dsDNA Well	14-5500-41	BFA3Y	0142

Use additional sheet(s) if necessary.

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

Date: _____

Signature: _____

(Please print name): _____

Name of Laboratory: _____

E-mail a signed, scanned copy or fax to:

Thermo Fisher Scientific
Thermo Fisher Diagnostics Oy
Ratastie 2 | FI-01620 Vantaa, Finland
Phone office +358 10 3292 110
Fax +358 10 3292 531

Area Manager Jari Siuro (jari.siuro@thermofisher.com) or
Sales & Application Specialist Hannakaisa Jaatinen (hannakaisa.jaatinen@thermofisher.com).