URGENT FIELD SAFETY NOTICE
EliA Sample Diluent, ImmunoCAP Specific IgA/IgG Sample Diluent

[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 voluntarily recalling certain lots of EliA Sample Diluent and ImmunoCAP Specific IgA/IgG Sample Diluent.

REASON FOR VOLUNTARY RECALL
There have been reports of instrument malfunctions for Phadia 250 due to deformed bottles in the below mentioned products and lots. The deformation of the bottle can cause an erroneous volume detection by the instrument which will result in insufficient aspiration of sample diluent, thus generating insufficient dilution of patient samples. The deformation is described as a flange or brim, located on the inside lower part of the vial opening.

The instrument malfunction due to deformed bottles could cause erroneous test results, mainly false positive, with regard to all EliA assays, and mainly falsely increased test results for ImmunoCAP IgG4/IgG assays.

The frequency of this bottle defect is very low and not every defective bottle will cause the error. An instrument malfunction caused by deformed bottles will generate the instrument error message *"3-145 RIGHT ARM LIQUID DETECTION BELOW LOWER LIMIT with Target 2"*. It is important that you review your records for the above mentioned error message as described further on in this notice.

RISK TO HEALTH:
The described error could cause erroneous test results for any of the above mentioned analytes. An erroneous test result means that the reported value will be higher or lower than the real value. This may cause a delay in a proper diagnosis, however, the probability of a serious adverse health consequence or serious deterioration in state of health due to a delayed diagnosis is estimated to be remote. In line with this, there have been no reports of a patient injury.

PRODUCT AND DISTRIBUTION INFORMATION:

Product Names, UDI (if applicable)	Product No.	Lot	Bottle Lot	Manufacturing Dates	Expiration Date (yyyy/mm/dd)
ImmunoCAP Specific IgA/IgG Sample Diluent (01)07333066000343 (17)180831(10)JPT7	10-9361-01	JPT7	AJLC9/ JPT6	2016-10-04	2019-09-30
ImmunoCAP Specific IgA/IgG Sample Diluent (01)07333066015910 (17)180930(10)JT48	10-9361-02	JT48	AJLCA/ JT47	2016-11-01	2019-10-31
EliA Sample Diluent (01)07333066013800 (17)190831(10)JM3Y	83-1023-01	JM3Y	BVXDR /JM3W	2016-08-30	2019-08-31
EliA Sample Diluent (01)07333066013800 (17)191031(10)JS0B	83-1023-01	JS0B	BVXDT /JS0A	2016-10-17	2019-10-31
EliA Sample Diluent (01)07333066013800 (17)190930(10)JP87	83-1023-01	JP87	BVXDS /JP83	2016-09-27	2019-09-30
EliA Sample Diluent (01)07333066013800 (17)190731(10)JK5N	83-1023-01	JK5N	BVXDP /JK5M	2016-08-02	2019-07-31
EliA Sample Diluent (01)07333066013800 (17)191130(10)JU9C	83-1023-01	JU9C	BVXD U/JU9B	2016-11-14	2019-10-30

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER:

- Stop using the affected lots of the above mentioned products
- Please, return or attest to scrapping of any unused products to the manufacturer and order replacement products free of charge.
- Review your records, if you find the instrument error message 3-145 RIGHT ARM LIQUID DETECTION BELOW LOWER LIMIT Target 2, please contact customer support at <insert phone number>.
- Fill in the Field Safety Notice return response on page 4 and return to the manufacturer by e-mail.

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 Competent Authority. 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

FIELD SAFETY NOTICE RETURN RESPONSE
Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION:
[Customer name
Attn:
Address]

EliA Sample diluent, ImmunoCAP Specific IgA/IgG Sample Diluent

I have read and understand the attached FSN and recall instructions: _____ (initials)

Error message 3-145 RIGHT ARM LIQUID DETECTION BELOW LOWER LIMIT with Target 2 seen? _____Yes _____No

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

If yes, please explain:

_____

_____

AFFECTED PRODUCT INFORMATION:

Product/Brand Name (UDI, if applicable)	Manufacturer's Product No.	Affected Lot	Bottle lot	Quantity in Inventory	Quantity Destroyed / Returned
ImmunoCAP Specific IgA/IgG Sample Diluent (01)07333066000343 (17)180831(10)JPT7	10-9361-01	JPT7	AJLC9/ JPT6		
ImmunoCAP Specific IgA/IgG Sample Diluent (01)07333066015910 (17)180930(10)JT48	10-9361-02	JT48	AJLCA/ JT47		
EliA Sample Diluent (01)07333066013800(17) 190831(10)JM3Y	83-1023-01	JM3Y	BVXDR /JM3W		
EliA Sample Diluent (01)07333066013800 (17)191031(10)JS0B	83-1023-01	JS0B	BVXDT /JS0A		
EliA Sample Diluent (01)07333066013800 (17)190930(10)JP87	83-1023-01	JP87	BVXDS /JP83		

Product/Brand Name (UDI, if applicable)	Manufacturer's Product No.	Affected Lot	Bottle lot	Quantity in Inventory	Quantity Destroyed / Returned
EliA Sample Diluent (01)07333066013800 (17)190731(10)JK5N	83-1023-01	JK5N	BVXDP /JK5M		
EliA Sample Diluent (01)07333066013800 (17)191130(10)JU9C	83-1023-01	JU9C	BVXD U/JU9B		

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:	

Document name Field Safety Notice (FSN) 2017-01_2EU Number 629665 Version 1.0

Issued by Anna Linde 2017-Jan-30 14:19 CET

Reviewed by Carina Magnusson 2017-Jan-30 15:16 CET

Approved by Fredrik Mirenborn 2017-Jan-30 17:19 CET
Release Date 2017-Jan-30 17:19 CET