

URGENT FIELD SAFETY NOTICE

ImmunoCAP Allergen f205, Herring

[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 one lot of ImmunoCAP Allergen f205, Herring.

REASON FOR THIS FIELD SAFETY NOTICE:

ImmunoCAP Allergen f205, Herring, lot 999G5 contains the wrong allergen. No customer complaints regarding this problem have been issued, and no adverse events have been reported.

RISK TO HEALTH:

The product malfunction could cause erroneous test results for the above mentioned product. 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 negligible.

PRODUCT INFORMATION:

Product Names	Product No.	Lot
ImmunoCAP Allergen f205, Herring	14-4837-01	999G5

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER:

- Please, scrap or return any unused products to the commercial organization and order replacement products free of charge
- All results obtained with the affected lot are recommended to be retested
- Fill in the Field Safety Notice return response and return to the manufacturer by e-mail



We appreciate your immediate attention to this recall. By returning the attached Acknowledgment Form you will facilitate our reporting of this matter to the Competent 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



FIELD SAFETY NOTICE RETURN RESPONSE
Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION:

[Customer name

Attn:

Address]

ImmunoCAP Allergen f205, Herring

I have read and understand the attached Field Safety Notice and recall instructions: _____ (initials)

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

If yes, please explain:

AFFECTED PRODUCT INFORMATION:

Product Name	Product No.	Lot	Quantity ordered	Quantity used	Quantity destroyed/returned
ImmunoCAP Allergen f205, Herring	14-4837-01	999G5			

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:	



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