

**URGENT QUALITY INFORMATION**  
**FIELD SAFETY CORRECTIVE ACTION**  
**ImmunoCAP Allergen f205, Herring**

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**Date:** 2017-07-21

**Purpose:**

Field Safety Corrective Action

**Distribution:**

For internal communication within the commercial units affected in Germany, Belgium, Denmark, Great Britain, Austria, France, Spain and Estonia.

**Product:**

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

**Description of the problem:**

ImmunoCAP Allergen f205, Herring, lot 999G5 contains the wrong allergen f342.

**Actions to be taken by the customer/user:**

- Scrap or return all affected products to the commercial organization and order replacement products free of charge
- All results obtained with the affected lot are recommended to be retested
- Return acknowledgement

**Actions to be taken by the manufacturer:**

**Actions – Commercial Unit**

- Communicate the Field Safety Notice ID FSN2017-07\_1 to the affected customers.
- Send the attached “FSCA Report form” to the authority in your country with the Field Safety Notice attached. Keep the evidence that you have made this submission to the local authority.
- Send the Commercial Unit Report to Global QA

**Actions – Manufacturing Site**

- Corrective actions have been initiated to prevent this from re-occurring



**Transmission of this Notification:**

Please ensure that this notice is shared with anyone who needs to be made aware within your organization, or to any organization on which this notification potentially has an impact. We apologize for any inconvenience this event may cause. If you have any questions, please contact us.

Contact/Questions:

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## Commercial unit report

### Product

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

### Report

I hereby confirm that we have:

- Informed affected customer about the content in FSN2017-07\_1.  
Yes  No

If No, reason:

- Sent required information to the authority.  
Yes  No

If No, reason:

If sent, we have saved evidence of communication with customer and submission to authorities.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

(Please print name): \_\_\_\_\_

Site: \_\_\_\_\_

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

[Name, dep] Fax no +46 18 16 38 75 or scan and e-mail signed copy to  
[vigilance.idd@thermofisher.com](mailto:vigilance.idd@thermofisher.com)



Document name Quality Information QI2017-07\_EU Number 640209 Version 1.0

Issued by Helena Forsberg 2017-Jul-21 12:13 CET

Reviewed by Carina Magnusson 2017-Jul-21 12:16 CET

Approved by Fredrik Mirenborn 2017-Jul-21 12:40 CET

Release Date 2017-Jul-21 12:40 CET

