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URGENT QUALITY INFORMATION

FIELD SAFETY CORRECTIVE ACTION ImmunoCAP Allergen f205, Herring

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

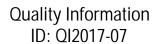
Actions to be taken by the manufacturer:

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



Approved by Fredrik Mirenborn 2017-Jul-21 12:40 CET Doc.no. 640209 Ver. 1.0 Page 2(4)



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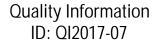
Transmission of this Notification:

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: Helena Forsberg Global QA helena.forsberg@thermofisher.com

Document approved by: Fredrik Mirenborn Director Global Quality Assurance **Immunodiagnostics** Thermo Fisher Scientific Uppsala, Sweden fredrik.mirenborn@thermofisher.com







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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 \(\subseteq \) No \(\subseteq \)
If No, reason:
 Sent required information to the authority. Yes \(\sum_{\cup No} \sum_{\cup No} \sum_{\cup No} \sum_{\cup No} \sum_{\cup No} \sum_{\cup No} \(\sum_{\cup 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



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