Urgent Field Safety Notice
ImmunoCAP Specific IgG/IgG4 i1 Control H
Field Safety Corrective Action

Date: December 22, 2015

Dear Customer,

We are writing to you concerning an issue affecting ImmunoCAP Specific IgG/IgG4 i1 Control H and to inform you of the mitigating measures to be taken.

Product affected:

ImmunoCAP Specific IgG/IgG4 i1 Control H (Art. No. 10-9475-01, 10-9475-02), all lots, used in combination with ImmunoCAP Allergen i1, Honey bee venom art.no 14-4143-01, lot 389B7 and 389B8 or 14-4153-23 lot BYVB7 and BYVB8.

Description of the problem:

When using ImmunoCAP specific IgG/IgG4 i1 Control H (Art. No. 10-9475-01, 10-9475-02), all lots, in combination with ImmunoCAP Allergen i1, Honey bee venom art.no 14-4143-01, lot 389B7 and 389B8 or 14-4153-23 lot BYVB7 and BYVB8 the ranges for mean concentration of IgG/IgG4 stated on the vial label of the quality control sample is incorrect.

The new measuring ranges for ImmunoCAP Specific IgG/IgG4 i1 Control H, all lots when used in combination with ImmunoCAP i1, lot 389B7 and 389B8 or BYVB7 and BYVB8 are:

- IgG4: 12 – 25 mg/l
- IgG: 24 - 47 mg/l

The problem is easily detected by the operator since the quality control samples will fail.

This issue affects the ImmunoCAP Specific IgG/IgG4 i1 Control H samples only; patient results for i1 are not affected by the lot number of ImmunoCAP Allergen i1, Honey bee venom, used to generate the assay result. No action needs to be taken in regards to past or current patient results for ImmunoCAP Allergen i1, Honey bee venom.

Methods affected by this Product Correction:

- ImmunoCAP Specific IgG
- ImmunoCAP Specific IgG4

Actions to be taken by the customer/user:

- Use the above stated measuring ranges for ImmunoCAP Specific IgG~~4~~/IgG4 i1 control H (Art. No. 10-9475-01, 10-9475-02), all lots when used in combination with ImmunoCAP Allergen i1, Honey bee venom art.no 14-4143-01, lot 389B7 and 389B8 or 14-4153-23 lot BYVB7 and BYVB8

- Fill in the ImmunoCAP Specific IgG~~4~~/IgG4 assay Corrective Action notice on page 3 and return to manufacturer.

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.

Phadia needs your assistance with our efforts to process this Field Safety Corrective Action. We are requesting that a responsible member of your laboratory sign and return a copy of the attached Acknowledgement Form to verify receipt of this letter. Please complete the last page of this letter and either scan/email or FAX it to:

TBD, commercial Organizations contact person:
Name
Address
Telephone
E-mail

We apologize for any inconvenience this may cause.

If you have any questions, please contact us.

Sincerely,

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ImmunoCAP Specific IgG/IgG4 Corrective Action

The information in the ImmunoCAP Specific IgG/IgG4 Field Safety Notice has been read and understood by our laboratory. We acknowledge that this information applies to the ImmunoCAP Specific IgG/IgG4 assay and will be communicated to all operators.

I hereby acknowledge receipt of this notification: FSN 2015-08 ImmunoCAP Specific IgG/IgG4

Date:_____

Signature:_____

(Please print name):_____

Name of
laboratory:_____

E-mail a signed, scanned copy or fax to (*to be defined by Commercial Organizations*):

Name
ImmunoDiagnostics
Thermo Fisher Scientific

Address

Office; Mobile; Fax

Email: xxxxxx@thermofisher.com