Urgent Field Safety Notice
ImmunoCAP ISAC sIgE 112
Corrective action

Date: October 14, 2014

Dear Customer,

The purpose of this letter is to inform you of the initiation of a corrective action related to a product performance issue.

Product affected:

ImmunoCAP ISAC sIgE 112, Art. No.: 81-1011-01
Our records show that your organization has received the affected product.

Description of the problem:

Customer complaints registered have reported false positive results for some components of ImmunoCAP ISAC sIgE 112. Additional investigations have confirmed that a subset of the allergen components on the ImmunoCAP ISAC chip could be subject to elevated background signals, see Table 1 below. For lots affected, see Table 2 below. The increased background levels could cause false positive results for some samples. No incidents have been reported. From the medical risk assessment, it has been concluded that the above described situation would not pose a risk to patient health as defined by the MEDDEV 2.12-1 guidance document.

Actions to be taken by user (laboratory):

- Re-evaluate test results generated from usage of any of the affected lots, as appropriate. Low to moderate positive signals in the range of 0.3-1.5 ISU-E could represent a false positive result.
- Evaluate whether false positive results could potentially have been reported, and as a consequence thereof, take on further communication to physicians or others, as deemed necessary.
- Would a need for retesting be identified, please contact your local representative for guidance.
- Remaining material from the above listed lots should be discarded. No return of product to the manufacturer is required.

Table 1. Affected allergen components

Aln g 1	Asp f 3	Cor a 1.0101	Pen m 2
Amb a 1	Asp f 6	Cor a 8	Pen m 4
Ana o 2	Blo t 5	Der p 2	Phl p 4
Api m 4	Bos d lactoferrin	Gal d 5	Phl p 6
Ara h 1	Can f 1	Gly m 4	Pla l 1
Ara h 3	Can f 3	Hev b 3	Pol d 5
Ara h 8	Che a 1	Ole e 1	Ves v 5
		Ole e 7	

Table 2. Affected kit lots

GNT3	GRZ9	GS8C	GTF8
GPGA	GS4W	GSLU	GTF7
GPGR	GS89	GSLY	GTHP
GR39	GRZD	GTEZ	GSY5
GPHN	GS39	GT8W	GTF1
GR7T	GRZE	GSRA	GTLL
GR4U	GS75	GT6Z	GUJP
GR7U	GS73	GTF5	GUJR
GR93	GS66	GSY6	GUJN
GRZC	GS8A	GT5E	GUJS

Transmission of this Field Safety Notice:

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 require your assistance with our efforts to process this corrective action. We are requesting that the appropriate member of your laboratory sign to verify receipt of this letter. Please complete the last page of this letter and either scan/email or fax it to:

Contact person:

TBD by each Commercial Organization:
Name
Address
Telephone
Name
E-mail

The undersigned confirms that this notice will be notified to the appropriate Regulatory Agency.

Signature (Commercial contact person signature)

_____

Role- Commercial Organization name
Name

Please contact your local representative if you have any questions or require any assistance regarding this corrective action. We sincerely regret any inconvenience that this action may cause and we appreciate your understanding as we take action to ensure product performance.

DATE:_____

RE: ImmunoCAP ISAC sIgE 112

Information in FSN 2014-03 has been received

Name of laboratory:

_____

Responsible party (please print):

_____

_____

I hereby acknowledge receipt of this notification: FSN2014-03.

_____
Signature

E-mail a signed, scanned copy or fax to (to be defined by Commercial Organization)**:**
Name
ImmunoDiagnostics
Thermo Fisher Scientific

Address

Office; Mobile; Fax

Email: xxxxxx@thermofisher.com

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