

Product Notification
ImmunoCAP Specific IgG/IgG4 i1 Control H

Date: October 25, 2016

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:

Art. No.	Art. Name	Vial No.	Vial Lot No.	UDI No.	Expiry date
10-9475-01	ImmunoCAP Specific IgG/IgG4 i1 Control H	34-2331-01	C6XAX or older	(01)07333066012414(17)170731(10)C6XAX or older	Lots with expiry date until July 2017
			C6XAX or newer	N/A	Lots with expiry date later than July 2017
10-9475-02	ImmunoCAP Specific IgG/IgG4 i1 Control H	34-2331-01	C6XAX or older	(01)07333066012414(17)170731(10)C6XAX or older	Lots with expiry date until July 2017
			C6XAX or newer	N/A	Lots with expiry date later than July 2017
14-4143-01	ImmunoCAP Allergen i1, Honey bee venom	N/A	389B7	(01)07333066001432(17)170731(10)389B7	2017-07-31
			389B8	(01)07333066001432(17)00000(10)389B8	2017-09-30
			389B9	(01)07333066001432(17)180331(10)389B9	2018-03-31
			389BA	(01)07333066001432(17)180531(10)389BA	2018-05-31
			389BB	Pending	Pending
14-4143-23	ImmunoCAP Allergen i1, Honey bee venom	N/A	BYVB7	N/A	2017-07-31
			BYVB8	N/A	2017-09-30
			BYVB9	N/A	2018-03-31
			BYVBA	N/A	2018-05-31
			BYVBB	Pending	Pending

Description of the problem:

In addition to the information provided in PN2015-08, the ranges stated below should be used for the combination of ImmunoCAP Allergen i1, Honey bee venom with ImmunoCAP Specific IgG/IgG4 i1 Control H. Affected lots are listed below.

	ImmunoCAP Specific IgG/IgG4 i1 Control H Art. No. 10-9475-01 & 10-9475-02 Vial lots with expiry date until July 2017 (C6XAX or older)	ImmunoCAP Specific IgG/IgG4 i1 Control H Art. No. 10-9475-01 & 10-9475-02 Vial lots with expiry date later than July 2017 (newer than C6XAX)
ImmunoCAP Allergen i1, Honey bee venom Art. No. 14-4143-01 Lots 389B7, 389B8, 389B9, 389BA & 389BB Art. No. 14-4143-23 Lots BYVB7, BYVB8, BYVB9, BYVBA & BYVBB	IgG4: 12 – 25 mg/l IgG: 24 - 47 mg/l	Ranges stated on the vial label
ImmunoCAP Allergen i1, Honey bee venom Art. No. 14-4143-01 All other lots Art. No. 14-4143-23 All other lots	Ranges stated on the vial label	Ranges stated on the vial label

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 Notification:

- ImmunoCAP Specific IgG
- ImmunoCAP Specific IgG4

Actions to be taken by the customer/user:

- Use the above stated measuring ranges for ImmunoCAP Specific IgG4/IgG4 i1 control H in combination with ImmunoCAP Allergen i1, Honey bee venom.
- Fill in the ImmunoCAP Specific IgG4/IgG4 assay Product Notice on page 4 and return to distributor.

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 Product Notice. 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:

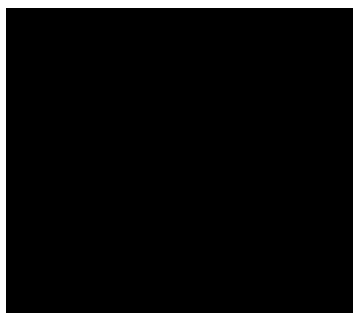
Edmund Yap
edmund.yap@biomed.com.sg
Mobile: 9101 8367

or *Sherlyn Kon*
sherlyn.kon@biomed.com.sg
Mobile: 9105 3321

Biomed Diagnostics Pte Ltd
18 Boon Lay Way #05-105/108
Tradehub 21
Singapore 609966

We apologize for any inconvenience this may cause.

If you have any questions, please contact us.



ImmunoCAP Specific IgG/IgG4 Product Notice

The information in the ImmunoCAP Specific IgG/IgG4 Product 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: PN 2015-08_2 ImmunoCAP Specific IgG/IgG4

Date: _____

Signature: _____

(Please print name): _____

Name and stamp of
laboratory: _____

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

Edmund Yap
edmund.yap@biomed.com.sg
Mobile: 9101 8367

or *Sherlyn Kon*
sherlyn.kon@biomed.com.sg
Mobile: 9105 3321

Biomed Diagnostics Pte Ltd
18 Boon Lay Way #05-105/108
Tradehub 21
Singapore 609966
Fax: 6298 4723