Product Notification
ImmunoCAP Specific IgE Control H lot CYYAC

July 14th, 2016

Dear Customer,

We are writing to you concerning an issue regarding ImmunoCAP Specific IgE Control H vial lot CYYAC. Precipitates have been identified in the vials and kit lots mentioned below. If samples containing precipitates are used, an increased frequency of functional disturbances (error messages e.g. clot error etc.) is to be expected in the instruments.

Product and distribution information:

This product notification applies to ImmunoCAP Specific IgE Control H with the following art no and lot no:

Kit Art no	Kit lot	Vial lot
10-9530-01	JBWA	CYYAC
10-9530-01	JEXG	CYYAC
10-9530-02	JB73	CYYAC
10-9530-02	JCW5	CYYAC
10-9530-02	JE3R	CYYAC
10-9530-41	JC9J	CYYAC

Reason for product correction:

Occurrence of precipitate in the control, such as in vial lot CYYAC, could give an increased frequency of functional disturbances in the instruments. However, in-house studies performed show no indication that the IgE results would be affected by the precipitates.

Actions to be taken by the customer/user:

Please review your internally stored reagents to determine whether your laboratory may have ImmunoCAP Specific IgE Control H from the kit lots mentioned above. If you still have vials or kits in house, we recommend that you discard them and place an order for new kits, free of charge. Please contact your local distributor for further information.

Actions to be taken by the manufacturer:

Corrective actions are initiated to prevent the problem from re-occurring.

Transmission of this Notification:

Please ensure that this product notification 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 may cause.

If you have any questions, please contact us.

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

Sincerely,

_____