Date: DD: MM: YYYY

Product Notification

For Attention to customers using
ImmunoCAP™ Allergen f279, Chilipepper and
ImmunoCAP™ Allergen Rf279, Chilipepper

Contact details of local representative	
Name	
Address	
Email address	
Telephone number	

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Product Notification

1. Information of affected device(s)	
1.1	Device Types(s) Reagent
1.2	Commercial name(s) ImmunoCAP™ Allergen f279, Chilipepper ImmunoCAP™ Allergen Rf279, Chilipepper
1.3	Unique Device Identifier(s) (UDI-DI) 07333066006581 07333066006598
1.4	Primary clinical purpose of device(s) ImmunoCAP Specific IgE is an in vitro test system for the quantitative measurement of allergen specific IgE in human serum or plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings and is to be used in clinical laboratories. ImmunoCAP Specific IgE is to be used with the instruments Phadia 100, Phadia 200, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.
1.5	Device Model/Catalogue/ part number(s) 14-5062-01 14-5062-10
1.6	Affected serial or lot number range BSDGK/RY8F, BSDGK/S9EE, BSDGK/SHE0, BSDGL/SMUS 668GK/RZHU, 668GK/S39D, 668GK/S9GR, 668GL/SRHC, 668GL/SY9A, 668GL/T5W3

2. Reason for Product Notification	
2.1	Description of the problem During manufacturing of ImmunoCAP Allergen f279, Chillipepper and ImmunoCAP Allergen Rf279, Chillipepper the incorrect species Capsicum annuum was used instead of Capsicum frutescens. A comparison study of positive samples on ImmunoCAP Allergen f279 produced with C. annuum and the correct species C. frutescens was performed and showed that the test results were comparable. Therefore, test results are not affected by this issue.
2.2	Health Hazard Evaluation The evaluation showed that no adverse health consequences are associated with the use of the affected lots.

3. Type of Action to mitigate the risk	
3.1	Action(s) to be taken by the user ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Patient follow up ☐ Review of patients' previous results ☐ Take note of amendment/reinforcement of instructions for use (IFU) ☐ Other ☒ None
3.2	Is customer reply required? No
3.3	Action(s) to be taken by the manufacturer ☐ Product removal (partial recall) ☐ Product removal (full recall) ☐ On-site device modification/ inspection ☐ Software upgrade ☐ IFU or labeling change ☐ Customer information only ☒ Other A CAPA has been initiated to prevent this from reoccurring. ☐ None

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4. General information		
4.1	Product Notification type	New
4.2	Further advice or information already expected in follow- up Product Notification?	No
4.3	Manufacturer information	
	Company name	Phadia AB
	Address	Rapsgatan 7P, P.O Box 6460 75137 Uppsala, Sweden
	SRN	SE-MF-000014170
4.4	This event has been evaluated against your country's current requirements for reportability to authorities. The conclusion is that this is not a reportable event.	
4.5	Name:	
	Title:	
	Signature:	

Transmission of this Product Notification
This Product Notification needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this Product Notification to other organizations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of eventual actions. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *

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