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Date: DD: MM: YYYY

Product Notification

For Attention to customers using ImmunoCAP Allergen f76, Allergen component nBos d 4 Alpha-lactalbumin, Milk

Contact details of local representative	
Name	
Address	
Email address	
Telephone number	

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1. Information of affected device(s)	
1.1	Device Types(s) Reagent
1.2	Commercial name(s) ImmunoCAP Allergen f76, Allergen component nBos d 4 Alpha-lactalbumin, Milk
1.3	Unique Device Identifier(s) (UDI-DI) 14-4522-01: 07333066004105 14-4522-22: N/A
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) 14-4522-01 14-4522-22
1.6	Affected serial or lot number range 14-4522-01: CTPBA, CTPBB, CTPBC, CTPBD 14-4522-22: CTTBA, CTTBB, CTTBD

2. Reason for Product Notification	
2.1	Description of the problem Several complaints have been registred due to unusually large mean difference observed for different lots of ImmunoCAP Allergen f76, Allergen component nBos d 4 Alpha-lactalbumin, Milk covered in UKNEQAS assessment 216. No malfunction was found for this issue, and the investigations concluded that the sample 216 from UKNEQAS was a rare type of sample. Further investigation showed that the deviating results were due to presence of nBos d lactoferrin (LF) in the purified nBos d 4. Presence of nBos d LF has not previously been observed in the starting material and therefore the purification process was not adapted to handle this protein. This issue may cause elevated results in the affected lots listed on page 2, of ImmunoCAP Allergen f76, Allergen component nBos d 4 Alpha-lactalbumin, Milk. The study with milk positive samples showed that 3,4 % of the samples changed from negative (<0,1 kUA/l) to low positive test results. None of these samples obtained a concentration above 0,35 kUA/l.
2.2	Probability of problem arising Milk positive samples were analyzed with nBos d 4 which contains nBos d LF and with further purified nBos d 4 coupled to ImmunoCAP. The probability that the presence of nBos d LF in ImmunoCAP Allergen f76, Allergen component nBos d 4 Alpha-lactalbumin, Milk may cause a false positive result is estimated to be 3.4 %.
2.3	Risk to patient/ users Internal investigation showed that 3,4 % of samples may change from negative (<0,1 kUA/l) to low positive test results. None of these obtained concentrations above 0,35 kUA/l. All tested patients are expected to be sensitized or positive to milk therefore it is not likely that use of the affected lots will cause adverse health consequences. A falsely elevated or positive food-allergen specific IgE result could cause unnecessary intervention such as a recommendation on avoidance of milk in question or prescription of an adrenaline auto-injector. This may lead to patient's inconvenience and discomfort.
2.4	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 ☐ Take note of amendment/reinforcement of instructions for use (IFU) ☒ Other • Please scrap affected lots and order a replacement product for free of charge. • Implement the content of this Product Notification within your organization. • Please consider if retesting of the samples is needed according to your internal operating procedures. • Sign and return Customer Reply form PN2022-12. ☐ None
3.2	Is customer reply required? Yes
3.3	Action(s) to be taken by the manufacturer ☐ Product removal ☐ On-site device modification/ inspection ☐ Software upgrade ☐ IFU or labeling change ☒ Other • Information will be sent out when new lots are available. • A CAPA has been initiated to prevent this from reoccuring. ☐ None

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4. General information		
4.1	Product Notification type New	
4.2	Manufacturer information	
	Company name	Phadia AB
	Address	Rapsgatan 7P, P.O Box 6460 75137 Uppsala, Sweden
	SRN	SE-MF-000014170
4.3	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.	
4.4	List of attachments/ appendices: 1. Customer reply form PN2022-12	
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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