FSN Ref: QA2022-15

Date: 07.12.2022

Urgent Field Safety Notice

For Attention to customers using Phadia™ 200 instrument

Contact details of local representative	
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Urgent Field Safety Notice (FSN)

Risk addressed by FSN

1. Information of affected device(s)	
1.1	Device Types(s) Phadia 200 instrument
1.2	Commercial name(s) Phadia 200 instrument
1.3	Unique Device Identifier(s) (UDI-DI) 07333066016900
1.4	Primary clinical purpose of device(s) Phadia 200 is a fully automated instrument including software to be used together with dedicated in vitro diagnostic tests. The instrument is designed to handle processing of samples, reagents and calculation of analytical results from the measurement values. Phadia 200 is intended to be used in clinical laboratories.
1.5	Device Model/Catalogue/ part number(s) 12-4300-00

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the problem

Several customer complaints have been registered questioning the accuracy of ImmunoCAP™ Tryptase results obtained on Phadia 200 instruments based on comparison to results for the same samples obtained on other Phadia instruments. Further investigation has shown that the Phadia 200 instrument does not meet specifications.

Examination of the Phadia 200 instrument showed a tendency to provide elevated tryptase measurements and that the magnitude of difference varied across the measurement range. Because of the variation across the measurement range, the specifications are not fulfilled and disqualify the Phadia 200 instruments from performing the ImmunoCAP Tryptase assay.

Sample concentration ranges (µg/l)	Average difference in results (%) between Phadia 200 and other Phadia instruments		
	Phadia 100	Phadia 250	Phadia 1000
1-10	+5	+6	-1
10-30	+8	+13	+9
30-100	+12	+20	+16
100-200	+2	+14	+6

A review of the conformance studies for all ImmunoCAP methods on the Phadia 200 instrument did not find a visible trend except for ImmunoCAP Tryptase. No other Phadia instruments are affected by this issue.

2.2 Predicted risk to patient/ users

When used to diagnose mast cell activation syndrome (MCAS), falsely elevated or positive (above limit of detection 1 µg/l) Tryptase test results may lead the physician to unnecessary search for the trigger or triggers. This may cause patient's inconvenience; additional physicians visit, consultation and unnecessary blood draw.

When ordered to aid in the diagnosis of Systemic mastocytosis (SM), falsely elevated or positive (above 20 µg/l) Tryptase test results may lead the physician to erroneously believe the patient has SM. As Tryptase is one of the minor criteria, it is expected that symptomatic treatment would not be based on elevated or positive Tryptase results only. This result may conflict with clinical signs and symptoms and the major and other minor diagnostic criteria. Further investigation would most likely be performed which may include additional invasive procedures such as bone marrow (BM) biopsy. BM biopsy is usually well tolerated, and it is expected that the patient will completely recover from the procedure.

2.3 Hazards giving rise to the FSCA

	The Phadia 200 instrument do not fulfill the current specifications for ImmunoCAP Tryptase assay and may provide elevated results. This could lead to additional invasive procedures such as bone marrow (BM) biopsy.

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 • Do not run ImmunoCAP Tryptase assays on the Phadia 200 instrument. • Please consider if retesting of the samples is needed according to your internal operating procedures. If needed, contact your local Thermo Fisher Scientific representative to extract ImmunoCAP Tryptase data generated by the Phadia 200 instrument. • If retesting is deemed necessary, please order a replacement free of charge. • If possible, transfer the Tryptase assay to another Phadia platform in the lab, if not possible contact your local Thermo Fisher Scientific representative for alternative solutions. • Please fill in the Customer reply form FSN2022-15 and return the response to the contact person as described. ☐ 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 Corrective and preventive actions (CAPA) have been initiated. ☐ None

4. General information		
4.1	FSN type	New
4.2	Further advice or information already expected in follow- up FSN?	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	The Competent (Regulatory) Authority of your country has been informed about this communication to customers	
4.5	List of attachments/ appendices: • QA2022-15 Customer reply form	
4.6	Name:	Mark Gantsovski
	Title:	Sales & Application Specialist
	Signature:	

Transmission of this Field Safety Notice
This notice 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 notice 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 the corrective action. 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.