FSN Ref: FSN2022-02

FSCA Ref: QA2022-02 FSCA

Date: 01: 04: 2022

Urgent Field Safety Notice

Phadia 200

For Attention of State Agency of Medicines

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

Phadia 200
Risk addressed by FSN

1. Information of affected device(s)	
1.1	Device Types(s) Phadia™ Instrument
1.2	Commercial name(s) Phadia 200
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
1.6	Affected serial or lot number range All serial numbers

2. Reason for Field Safety Corrective Action (FSCA)	
2.1	Description of the problem An issue in the Phadia 200 software can cause the pipette to be placed too high above the dilution plate. This may cause the sample and diluent not being mixed properly and/or splashing of sample into other dilution wells. This can cause results to be between 7-230 % of the true value and may cause false negative or false positive results. ImmunoCAP™ and EliA™ test results may be affected if the following dilutions and tube settings are used: • 1:50 • 1:100 • 1:200 • Tube setting with a bottom thickness >5 mm ImmunoCAP and EliA tests that includes sample dilution according to these criteria are listed in appendix 1.
2.2	Hazards giving rise to the FSCA The issue may give false test results which may lead to the necessity of medical or surgical intervention. No residual risk for false test results if action is taken.
2.3	Probability of problem arising The frequency of possibly affected EliA tests when using tube settings with a bottom thickness >5 mm was estimated to be: • 6 % (7908 possibly affected tests / 131 370 total number of tests) For ImmunoCAP Specific IgG, the frequency of possibly affected tests when using tube settings with a bottom thickness >5 mm was estimated to be: • 7 % (358 possibly affected tests / 5000 total number of tests)
2.4	Predicted risk to patient/ users The probability for serious injury due to falsely decreased or increased EliA or ImmunoCAP Specific IgG results is estimated to be remote

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 A member of our Technical Support staff will contact you to schedule a visit to correct your instrument's tube settings and to investigate and inform you of possibly affected test results. If any possibly affected test results are identified, please determine if retesting of the samples is needed according to your internal operating procedures. Sign and return Customer Reply form FSN2022-02. ☐ 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 to prevent this from recurring. The tube settings must be checked and changed on the Phadia 200 instrument. A search for potentially incorrect test results should be performed. ☐ None

4. General information		
4.1	FSN type	New
4.2	Manufacturer information	
	Company name	Phadia AB
	Address	Rapsgatan 7P, PO Box 6460 75137 Uppsala, Sweden
4.3	The Competent (Regulatory) Authority of your country has been informed about this communication to customers	
4.4	List of attachments/ appendices: • List of tests that may be affected by QA2022-02 • Customer Reply Form FSN2022-02	
4.5	Name:	Mark Gantsovski
	Title:	Sales and Application Specialist
	Signature: