FSN Ref: QA2023-03

Date: DD: MM: YYYY

Urgent Field Safety Notice

For Attention to customers using Phadia™ 2500E, Phadia 2500EE, Phadia 5000E and Phadia 5000E+E

Contact details of local representative	
Name	
Address	
Email address	
Telephone number	

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Urgent Field Safety Notice (FSN)

Risk addressed by FSN

1. Information of affected device(s)	
1.1	Device Types(s) EliA Gliadin^{DP} IgG Well Phadia 2500E instrument Phadia 2500EE instrument Phadia 5000E instrument Phadia 5000E+E instrument
1.2	Commercial name(s) EliA Gliadin^{DP} IgG Well Phadia 2500E Phadia 2500EE Phadia 5000E Phadia 5000E+E
1.3	Unique Device Identifier(s) (UDI-DI) 07333066010847 (EliA Gliadin^{DP} IgG Well 14-5539-01) 07333066020839 (EliA Gliadin^{DP} IgG Well 14-5539-41) 07333066020921 (Phadia 2500E instrument) 07333066020938 (Phadia 2500EE instrument) 07333066020907 (Phadia 5000E instrument) 07333066020914 (Phadia 5000E+E instrument)
1.4	Primary clinical purpose of device(s) EliA Gliadin^{DP} IgG is intended for the in vitro quantitative measurement of IgG antibodies directed to gliadin in human serum or plasma to aid in the diagnosis of celiac disease. EliA Gliadin^{DP} IgG uses the EliA IgG method on the instrument Phadia 2500/5000.
1.5	Device Model/Catalogue/ part number(s) 14-5539-01 (EliA Gliadin^{DP} IgG Well IgG Well) 14-5539-41 (EliA Gliadin^{DP} IgG Well IgG Well) 12-4100-01 (Phadia 2500E) 12-4100-02 (Phadia 2500EE) 12-4000-01 (Phadia 5000E) 12-4000-02 (Phadia 5000E+E)
1.6	Software version Phadia Prime 2.6.11 (method update 60610)

1.7	Affected serial or lot number range EliA Gliadin^{DP} IgG Well- N/A This issue is not lot dependent 12-4100-01: N00113, N00121, N00125, N00126, N00130, N00132, N00142, N00143, N00148, N00149, N00150, N00151, N00152, N00153, N00167, N00168, N00203, N00204, N00205, N00206, N00207, N00215, N00216, N00217, N00222, N00223, N00226, N00227, N00228, N00231, N00240, N00246, N00249, N00250, N00255, N00258, N20006, N20005, N20007, N20010, N01618 12-4100-02: N00174, N00175, N00176, N00177, N00197, N00198, N00209, N00218, N00220, N00236, N00244, N00245, N00251, N00252, N00253, N00254, N20001, N20002, N20003, N20004, N20016 12-4000-01: N/A No instrument installed at customer 12-4000-02: N00147, N00161

2. Reason for Field Safety Corrective Action (FSCA)	
2.1	Description of the problem Higher reported results when running EliA Gliadin^{DP} IgG Well on the instruments Phadia 2500E, Phadia 2500EE, Phadia 5000E and Phadia 5000E+E compared to running EliA Gliadin^{DP} IgG Well on Phadia 250 instrument have been observed by a customer and confirmed in customer data. An internal study has been performed running the EliA Gliadin^{DP} IgG Well on Phadia 2500E and Phadia 250. The study showed an increase of up to 29.4% in test results on the Phadia 2500E compared to the Phadia 250 with instrument diluted samples and an increase of up to 20% in test results with pre-diluted samples. For all samples in this study there were no reported changes from negative to positive or positive to negative results between the instrument types. Only switches from negative to equivocal or equivocal to positive were seen as the assay specific equivocal range covers 30%. It cannot be excluded, however, that samples will not jump from negative to positive result due to general variations on the instruments Phadia 2500E, Phadia 2500EE, Phadia 5000E and Phadia 5000E+E and wells, instrument handling, and other known factors. There is no evidence of a malfunction for the EliA Gliadin^{DP} IgG Well itself or for specific well lots used, nor any evidence of a malfunction for affected Phadia instruments themselves. However, the investigation does point to a malfunction when using a specific combination of assay/instruments/Phadia Prime 2.6.11 and/or method update 60610/61610 or later that generates biased test results as compared to Phadia 250. The cause of the detected bias between the Phadia 2500E and Phadia 250 results for EliA Gliadin^{DP} IgG Well assay is being investigated further in corrective and preventive actions (CAPA) initiated due to this issue.

2.2	Probability of problem arising EliA Gliadin^{DP} IgG results generated on the instruments Phadia 2500E, Phadia 2500EE, Phadia 5000E and Phadia 5000E+E from the date of revised concentration factor implementation will produce higher sample test results when compared to the Phadia 250.
2.3	Predicted risk to patient/ users Falsely elevated or positive DGP-IgG results may lead the physician to erroneously believe the patient has CD when the patient is IgA deficient. When used for diagnosis, a gluten-free diet may be recommended in error. This may lead to patient's inconvenience and unnecessary follow-up doctors visit and blood draw.
2.4	Hazards giving rise to the FSCA Running EliA Gliadin^{DP} IgG on Phadia 2500E, Phadia 2500EE, Phadia 5000E and Phadia 5000E+E with detected positive bias may contribute to reporting of falsely elevated patient results.

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) ☐ None ☒ Other 1. Review instrument record logs to determine if any positive test results for EliA Gliadin^{DP} IgG may be affected by this issue according to your internal procedure. • Contact Technical Support who can further assist in collecting log files and aid in identifying the potentially impacted test results. *Log files may only be available for analysis for a limited timeframe of the Phadia Laboratory System due to storage and maintenance restrictions and may not cover the entire timeframe of the Instrument message log.* 2. Use of the EliA Gliadin^{DP} IgG Well on Phadia 2500E, Phadia 2500EE, Phadia 5000E and Phadia 5000E+E Phadia™ can continue as detailed in the user manual and the DfU with the following recommendations: i. For EliA Gliadin^{DP} IgG results that fall in the range of ≥10 to ≤13 EliA U/mL (due to risk of false positive EliA Gliadin^{DP} IgG results): a. Verify positive EliA Gliadin^{DP} IgG results using a Phadia 250 instrument if available. Use the result generated on the Phadia 250 to report patient results in line with the user manual and DfU. b. If you do not have direct access to a Phadia 250 instrument in your laboratory, please contact your local Thermo Fisher Scientific representative for further advice. c. As a secondary option, you may wish to verify positive EliA Gliadin^{DP} IgG results by running EliA Celikey IgG on your existing Phadia 2500E, Phadia 2500EE, Phadia 5000E and Phadia 5000E+E. It is important to note that EliA Celikey IgG is not a direct alternative for EliA Gliadin^{DP} IgG and results

	generated are not readily interchangeable. Both EliA tests are designed to assist in the diagnosis of celiac disease. Further scientific background on this recommendation can be provided by your local Thermo Fisher Scientific EliA contact. ii. For Gliadin^{DP} IgG results ≤10 to ≥13 EliA U/mL generated on Phadia 2500E, Phadia 2500EE, Phadia 5000E and Phadia 5000E+E, the negative (≤10) or positive (≥13) judgement compared to a Phadia 250 is not impacted by the instrument bias and therefore these values can be reported according to the Interpretation of Test Results section on the Gliadin^{DP} IgG DfU.
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 ☐ None ☒ Other 1. Corrective and preventive actions (CAPA) have been initiated.

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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: • Customer Reply Form QA2023-03	
4.6	Name:	
	Title:	
	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.

Document name Field Safety Notice(FSN)/Recall Letter QA2023-03 EU and RoW
Number 783338 Version 2.0

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Release Date 2023-Apr-19 17:17 CET

Customer Reply Form FSN ID: QA2023-03

1. Field Safety Notice (FSN) information	
FSN Reference number	QA2023-03
FSN Date	XXXX-XX-XX
Product/ Device name	EliA GliadinDP IgG Well Phadia 2500E instrument Phadia 2500EE instrument Phadia 2500EE instrument Phadia 5000E instrument Phadia 5000E+E instrument
Product Code(s)	14-5539-01 (EliA GliadinDP IgG Well IgG Well) 14-5539-41 (EliA GliadinDP IgG Well IgG Well) 12-4100-01 (Phadia 2500E) 12-4100-02 (Phadia 2500EE) 12-4000-01 (Phadia 5000E) 12-4000-02 (Phadia 5000E+E)
Batch/Serial Number (s)	EliA GliadinDP IgG Well- N/A This issue is not lot dependent 12-4100-01: N00113, N00121, N00125, N00126, N00130, N00132, N00142, N00143, N00148, N00149, N00150, N00151, N00152, N00153, N00167, N00168, N00203, N00204, N00205, N00206, N00207, N00215, N00216, N00217, N00222, N00223, N00226, N00227, N00228, N00231, N00240, N00246, N00249, N00250, N00255, N00258, N20006, N20005, N20007, N20010, N01618 12-4100-02: N00174, N00175, N00176, N00177, N00197, N00198, N00209, N00218, N00220, N00236, N00244, N00245, N00251, N00252, N00253, N00254, N20001, N20002, N20003, N20004, N20016 12-4000-01: N/A No instrument installed at customer 12-4000-02: N00147, N00161

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organization		
☐	I confirm receipt of the FSN and that I read and understood its content.	Customer to complete or enter N/A
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
☐	Other Action (Define):	Customer to complete or enter N/A
☐	I am not affected by this issue.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to complete or enter N/A
Print Name		
Signature		
Date		

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Document name Customer reply form QA2023-03
Number 783339 Version 1.0

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