FSN Ref: QA2023-05

Date: DD: MM: YYYY

Urgent Field Safety Notice

For Attention to customers using EliA GBM Well

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 GBM Well
1.2	Commercial name(s) EliA GBM Well
1.3	Unique Device Identifier(s) (UDI-DI) 14-5514-01: 07333066010670 14-5514-10: N/A 14-5514-41: 07333066018553
1.4	Primary clinical purpose of device(s) Intended use: The EliA GBM Wells are part of the EliA IgG System. They are intended for the in vitro quantitative measurement of IgG antibodies to α3 chain of collagen IV in human serum and plasma as an aid in the clinical diagnosis of Goodpasture syndrome and anti-GBM disease. EliA GBM uses the EliA IgG method on Phadia instruments.
1.5	Device Model/Catalogue/ part number(s) 14-5514-01 14-5514-10 14-5514-41
1.6	Affected serial or lot number range All lots available on the market

2. Reason for Field Safety Corrective Action (FSCA)	
2.1	Description of the problem Several customer complaints have been reported where specific samples produced false positive EliA GBM results. An investigation confirmed that a positive signal was present when these samples were tested for coating-solution reactivity using EliA wells without antigen. The probable root cause is an unspecific reaction towards a BSA component in the coating solution used in the EliA GBM Well. There has been no change in design or component of BSA used in the EliA GBM Well. There is indication of a malfunction on EliA GBM Well due to a reaction towards BSA component in the coating solution as evidenced by increase in the number of relevant complaints and reports of affected samples. This malfunction occurs on the EliA GBM Well regardless of the Phadia Laboratory System™ used for testing.
2.2	Probability of problem arising There is a known inherent risk due to assay design that may contribute to product risk for specific samples containing anti-BSA antibodies. A definitive clinical diagnosis should not be based on the results of a single diagnostic method but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2.3	Predicted risk to patient/ users Falsely elevated or positive anti-GBM results may lead the physician to erroneously believe the patient has anti-GBM disease. This may cause a delay in the differential diagnosis of patients with glomerulonephritis and a delay in specific therapy. Under treatment, a falsely elevated result may cause unnecessary prolonged treatment, e.g. additional plasmapheresis, or an infusion of corticosteroids and/or immunomodulators. Plasmapheresis may lead to severe and life-threatening episode. In case of conflicting evidence from other investigations with falsely elevated or positive anti-GBM results, the physician may have to perform a kidney biopsy to confirm the diagnosis before treating the patient. This may also lead to a life-threatening serious adverse event (e.g. hemorrhage).
2.4	Hazards giving rise to the FSCA There is a known inherent risk due to assay design that may contribute to false positive EliA GBM Well results for specific samples containing anti-BSA antibodies.

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 1. The recommended action is a review of previously reported EliA GBM results produced on a Phadia Laboratory System. If required, instrument record logs can be reviewed to determine if any positive test results for EliA GBM may be affected by this issue. Customers/users should establish if further action is required according to their internal procedure. • Contact Thermo Fisher Scientific Technical Support who can further assist in collecting instrument 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.* The CAPA is on-going and until a resolution has been implemented and confirmed, Phadia AB recommend the following guidance to EliA GBM customers/users: 2. Use of the EliA GBM Well can continue as detailed in the user manual and the DfU with the following recommendations: i. For EliA GBM positive test results (>10 EliA U/ml): a) Verify positive EliA GBM results (>10 EliA U/ml) using an alternative method. b) If you do not have direct access to an alternative GBM method, please contact your local Thermo Fisher Scientific representative for further advice. ii. EliA GBM results ≤10 U/mL are not impacted by this issue and therefore these values can be reported according to the Interpretation of Test Results section on the EliA GBM DfU. ☐ 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 1. Corrective and preventive actions (CAPA) have been initiated. ☐ None

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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	
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.

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