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)<br><br>EliA GBM Well |
| 1.2 | Commercial name(s)<br><br>EliA GBM Well |
| 1.3 | Unique Device Identifier(s) (UDI-DI)<br><br>14-5514-01: 07333066010670<br>14-5514-10: N/A<br>14-5514-41: 07333066018553 |
| 1.4 | Primary clinical purpose of device(s)<br><br>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)<br><br>14-5514-01<br>14-5514-10<br>14-5514-41 |
| 1.6 | Affected serial or lot number range<br><br>All lots available on the market |

| 2. Reason for Field Safety Corrective Action (FSCA) | |
|---|---|
| 2.1 | Description of the problem<br><br>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.<br>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.<br><br>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<br><br>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<br><br>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.<br>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<br><br>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<br>☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device<br>☐ On-site device modification/inspection<br>☐ Follow patient management recommendations<br>☐ Take note of amendment/reinforcement of instructions for use (IFU)<br>☒ Other<br>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.<br>• Contact Thermo Fisher Scientific Technical Support who can further assist in collecting instrument log files and aid in identifying the potentially impacted test results.<br><br>*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.*<br><br>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:<br><br>2. Use of the EliA GBM Well can continue as detailed in the user manual and the DfU with the following recommendations:<br>i. For EliA GBM positive test results (>10 EliA U/ml):<br>a) Verify positive EliA GBM results (>10 EliA U/ml) using an alternative method.<br>b) If you do not have direct access to an alternative GBM method, please contact your local Thermo Fisher Scientific representative for further advice.<br>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.<br>☐ None |
| 3.2 | Is customer reply required?<br>Yes |
| 3.3 | Action(s) to be taken by the manufacturer<br>☐ Product removal ☐ On-site device modification/ inspection<br>☐ Software upgrade ☐ IFU or labeling change<br>☒ Other<br>1. Corrective and preventive actions (CAPA) have been initiated.<br>☐ 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<br>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:<br><br>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)<br><br>Please transfer this notice to other organizations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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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**Quality Information**
Field Safety Notice
EliA GBM Well

**Purpose:**
Quality Information about FSN/recall letter QA2023-05

**Distribution:**
Australia, Austria, Bahrain, Belgium, Bolivia, Bosnia-Herzegovina, Botswana, Brazil, Canada, Chile, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Djibouti, Estonia, Finland, France, Germany, Great Britain, Greece, Hong Kong, Iceland, India, Ireland, Italy, Japan, Kazakhstan, Lithuania, Luxembourg, Malaysia, Martinique, Mexico, Netherlands, New Zealand, Norway, Philippines, Poland, Portugal, Qatar, Romania, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia and USA.

**Product:**

| Product | Material number | Affected Lot |
|---|---|---|
| EliA GBM Well | 14-5514-01 | All lots available on the market |
| EliA GBM Well | 14-5514-10 | |
| EliA GBM Well | 14-5514-41 | |

**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 test.

There is indication of a malfunction on EliA GBM Well due to a reaction towards BSA component in the coating solution as evidenced by the 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.

There have been no reports of adverse events due to this issue and 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. Phadia AB has determined the probability of serious or medically reversible adverse health consequences to be remote and determined this to be a reportable field action.

**Actions to be taken by the customer/user:**

1. The recommended action is a review of previously reported results for EliA GBM 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 procedures.
   - 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.

**Actions to be taken by the Commercial organization**

1. Send the Commercial organization initial report to Global QA, as a confirmation that the information has been received.
2. Send the information as described in the Field Safety Notice FSN2023-05 to your customer(s) currently using EliA GBM Well.
3. Identify all new EliA GBM Well customers. Make sure that the information regarding this issue is implemented in their laboratory until any corrective actions are available for implementation.
4. Send the attached “FSCA Report form” to the authority in your country with the Field Safety Notice attached. Keep the evidence that you have made this submission to the local authority.
5. Identify and recommend an alternative method which could be used to verify positive EliA GBM samples for affected customers who do not have an alternative method in their laboratory.
6. Send the commercial organization final report to Global QA, when communication with customers and authorities have been performed.

**Actions to be taken by the manufacturer:**

1. Corrective and preventive actions (CAPA) have been initiated.

**Transmission of this Notification**:

Please ensure that this notice is shared with anyone who needs to be made aware within your organization, or to any organization on which this notification potentially has an impact.
We apologize for any inconvenience this event may cause. If you have any questions, please contact us.

Contact/Questions:
vigilance.idd@thermofisher.com

**Commercial organization initial report**
Field Safety Notice
EliA GBM Well

- I hereby acknowledge that we have received this QI and FSN/Recall Letter QA2023-05 and FSCA report:

  Yes ☐

Date:_____

Signature:_____

(Please print name):_____

Country/countries:_____

**E-mail a signed, scanned copy to:** vigilance.idd@thermofisher.com

**Commercial organization final report**
Field Safety Notice
EliA GBM Well

I hereby confirm that the following has been performed:

- Informed affected customer about the content in FSN/Recall Letter QA2023-05.

  Yes ☐ No ☐

  If No, reason:

- Customer response rate 100 %

  Yes ☐ No ☐

  If No, give actual response rate:
  Evidence of a minimum of three faith efforts to contact the customers is saved.

- Sent required information to the authority.

  Yes ☐ No ☐

  If No, reason:
  Evidence of communication with authorities is saved.

Date:_____

Signature:_____

(Please print name):_____

Country/countries:_____

**E-mail a signed, scanned copy or fax to:** vigilance.idd@thermofisher.com

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# Customer Reply Form FSN ID: QA2023-05

| 1. Field Safety Notice (FSN) information | |
|---|---|
| FSN Reference number* | QA2023-05 |
| FSN Date | XXXX-XX-XX |
| Product/ Device name | EliA GBM Well |
| Product Code(s) | 14-5514-01<br>14-5514-10<br>14-5514-41 |
| Batch/Serial Number (s) | All lots available on the market |

| 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 Organisation | | |
|---|---|---|
| ☐ | 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): | |
| ☐ | I do not have any affected devices. | |
| ☐ | I have a query please contact me (e.g. need for replacement of the product). | |
| 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.

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