

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**

| <b>1. Information of affected device(s)</b> |  |
|---|--|
| 1.1   | Device Types(s)<br><br>Phadia 200 instrument   |
| 1.2   | Commercial name(s)<br><br>Phadia 200 instrument  |
| 1.3   | Unique Device Identifier(s) (UDI-DI)<br><br>07333066016900   |
| 1.4   | Primary clinical purpose of device(s)<br><br>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)<br><br>12-4300-00   |

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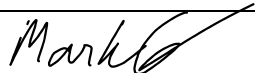
| <b>2. Reason for Field Safety Corrective Action (FSCA)</b> |  |            |             |                                    |   |  |  |            |            |             |      |    |    |    |       |    |     |    |        |     |     |     |         |    |     |    |
|--|--|------------|-------------|------------------------------------|---|--|--|------------|------------|-------------|------|----|----|----|-------|----|-----|----|--------|-----|-----|-----|---------|----|-----|----|
| 2.1  | <p>Description of the problem</p> <p>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.</p> <p>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.</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th rowspan="2">Sample concentration ranges (µg/l)</th> <th colspan="3">Average difference in results (%) between Phadia 200 and other Phadia instruments</th> </tr> <tr> <th>Phadia 100</th> <th>Phadia 250</th> <th>Phadia 1000</th> </tr> </thead> <tbody> <tr> <td>1-10</td> <td>+5</td> <td>+6</td> <td>-1</td> </tr> <tr> <td>10-30</td> <td>+8</td> <td>+13</td> <td>+9</td> </tr> <tr> <td>30-100</td> <td>+12</td> <td>+20</td> <td>+16</td> </tr> <tr> <td>100-200</td> <td>+2</td> <td>+14</td> <td>+6</td> </tr> </tbody> </table> <p>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.</p> |            |             | 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 |
| 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          |                                    |   |  |  |            |            |             |      |    |    |    |       |    |     |    |        |     |     |     |         |    |     |    |
| 2.2  | <p>Predicted risk to patient/ users</p> <p>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.</p> <p>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.</p>   |            |             |                                    |   |  |  |            |            |             |      |    |    |    |       |    |     |    |        |     |     |     |         |    |     |    |
| 2.3  | <p>Hazards giving rise to the FSCA</p>   |            |             |                                    |   |  |  |            |            |             |      |    |    |    |       |    |     |    |        |     |     |     |         |    |     |    |

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|--|---|
|  | 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. |
|--|---|

|   |  |
|---|--|
| <b>3. Type of Action to mitigate the risk</b> |  |
| 3.1   | <p>Action(s) to be taken by the user</p> <p><input type="checkbox"/> Identify Device   <input type="checkbox"/> Quarantine Device   <input type="checkbox"/> Return Device   <input type="checkbox"/> Destroy Device</p> <p><input type="checkbox"/> On-site device modification/inspection</p> <p><input type="checkbox"/> Follow patient management recommendations</p> <p><input type="checkbox"/> Take note of amendment/reinforcement of instructions for use (IFU)</p> <p><input checked="" type="checkbox"/> Other</p> <ul style="list-style-type: none"> <li>• Do not run ImmunoCAP Tryptase assays on the Phadia 200 instrument.</li> <li>• 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.</li> <li>• If retesting is deemed necessary, please order a replacement free of charge.</li> <li>• 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.</li> <li>• Please fill in the Customer reply form FSN2022-15 and return the response to the contact person as described.</li> </ul> <p><input type="checkbox"/> None</p> |
| 3.2   | <p>Is customer reply required?</p> <p>Yes</p>  |
| 3.3   | <p>Action(s) to be taken by the manufacturer</p> <p><input type="checkbox"/> Product removal   <input type="checkbox"/> On-site device modification/ inspection</p> <p><input checked="" type="checkbox"/> Software upgrade   <input checked="" type="checkbox"/> IFU or labeling change</p> <p><input checked="" type="checkbox"/> Other Corrective and preventive actions (CAPA) have been initiated.</p> <p><input type="checkbox"/> None</p>   |

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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><ul style="list-style-type: none"> <li>• QA2022-15 Customer reply form</li> </ul> |   |
| 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.