Quality Information
Phadia™ 200 performance of the ImmunoCAP™ Tryptase assay

Purpose:
Quality Information about Field Safety Notice, FSN2022-15.

Distribution:
Anguilla, Australia, Austria, Bahrain, Belarus, Belgium, Bolivia, Bosnia-Herzegovina, Botswana, Brazil, Chile, Colombia, Croatia, Czech Republic, Denmark, Djibouti, Ecuador, Estonia, Finland, France, Georgia, Germany, Greece, Guatemala, Hong Kong, India, Ireland, Japan, South Korea, Latvia, Lithuania, Malaysia, Mauritius, Netherlands Antilles, Panama, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, Ukraine, United Arab Emirates, United Kingdom, and Uzbekistan.

Product:

Product	Material number	Affected Serial Number
Phadia 200	12-4300-00	All serial numbers

Description of the problem:
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.

The Phadia 200 instrument met specifications during the original qualification study of the ImmunoCAP Tryptase assay, as determined by mean performance differences between Phadia instruments. Since then, the specifications have been updated requiring examination of data trends. Examination of this study's dataset showed a tendency for the Phadia 200 instrument 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 current specifications are not fulfilled and disqualify the Phadia 200 instruments from performing the ImmunoCAP Tryptase assay.

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

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.

The probability of serious adverse health consequences is determined to be not likely. This field action is determined to be reportable.

Actions to be taken by the customer/user:

- Do not run ImmunoCAP Tryptase assays on the Phadia 200 instrument.
- 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.
- If retesting is deemed necessary, please order a replacement free of charge.
- 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.
- Please fill in the Customer reply form FSN2022-15 and return the response to the contact person as described.

Actions to be taken by the manufacturer:

- A CAPA, CA21-00031 has been initiated and investigation is ongoing.
- Software and labelling will be updated in accordance with this field action.
- Send out Service Bulletin 178 that describes how to identify possibly affected results.
- Provide a Frequently Asked Questions (FAQ) information resource and conduct internal information sessions for COs. Details to be provided via a Marketing Information bulletin and the Marketing Buzz newsletter.

Actions – Commercial organization

- Send the Commercial organization initial report to Global QA, see page 3, as a confirmation that the information has been received.
- Send the commercial organization final report to Global QA, see page 4, when communication with customers and authorities has been performed.
- If needed, refer to Service Bulletin 178 to help customers identify possibly affected results.

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
Phadia™ 200 performance of the ImmunoCAP™ Tryptase assay

- I hereby acknowledge that we have received this QI and FSN2022-15 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
Phadia™ 200 performance of the ImmunoCAP™ Tryptase assay

I hereby confirm that the following has been performed:

- Informed affected customer about the content in FSN2022-15.

  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 to: vigilance.idd@thermofisher.com

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