

Quality Information

Product Notification

ImmunoCAP Total IgE, ImmunoCAP Specific IgE and ViewAllergy.

Purpose:

Quality Information about Product Notification, PN2021-06.

Distribution:

Afghanistan, Algeria, Argentina, Armenia, Aruba, Australia, Austria, Azerbajdzjan, Bahrain, Belarus, Belgium, Bosnia-Herzegovina, Brazil, Bulgaria, Canada, Cape Verde, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Dominican Republic, Dutch Antilles, Egypt, El Salvador, Estonia, Finland, France, Georgia, Germany, Great Britain, Greece, Greenland, Guatemala, Hong Kong, Hungary, Iceland, India, Indonesia, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kuwait, Kyrgyzstan, Laos, Lebanon, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malaysia, Maldives, Malta, Mauritius, Mexico, Moldavia, Montenegro, Morocco, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Norway, Oman, Panama, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russia, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sri Lanka, Sweden, Switzerland, Tadzhikistan, Taiwan, Thailand, Tunisia, Turkey, Turkmenistan, Ukraine, United Arab Emirates, Uruguay, US, Uzbekistan, Venezuela, Vietnam.

Affected products

For affected products see appendix 1.



Description of the problem:

An increased frequency of incoming complaints where the customer noticed dispensing errors due to capsules stuck in carriers has been reported during Q3 2021.

Small deformations of capsules may occasionally occur during manufacturing. The small deformations may cause capsules to get stuck in the carrier which can lead to dispensing problems in the Phadia instruments. This will not lead to incorrect test results.

One of the production equipments had a confirmed problem that damaged the capsules intermittently under a period of time. The deformation, located underneath the flange of the capsule, may cause the capsules to get stuck inside the carriers. In house testing showed that up to 8 % of the carriers listed in Appendix 1 may be affected by the issue and could cause a disturbance for the customer.

If a dispensing error caused by a stuck capsule would occur in the Phadia instrument (P200, P250, P1000 and P2500/P5000)

- The affected carrier will be removed to the storage area.
- The affected carrier will be marked as unusable in the software and will not be available for reuse.
- If there is a new ImmunoCAP carrier (for the same allergen) available in the storage, this will be used, and the process continues accordingly.
- If there is no other ImmunoCAP carrier (for the same allergen) available, no ImmunoCAP test can be dispensed. No test results will be generated for the affected ImmunoCAP test. This may cause a delay in test results. The process will continue with the other allergens.

Phadia 100 is manually handled and the process cannot proceed until the affected carrier is replaced.

- If there is a new ImmunoCAP carrier (for the same allergen) available, this can be used, and the process continues accordingly.
- If there is no other ImmunoCAP carrier (for the same allergen) available, the process will stop unless an ImmunoCAP dummy is used. No test results will be generated for the affected ImmunoCAP test. This may cause a delay in test results.

The probability for serious injury due to delayed test results are estimated to be remote.

There have been no reports of adverse events as a result of the dispensing errors caused by the deformed capsules.



Actions to be taken by the customer/user:

- If you discover capsules stuck in carriers from the affected lots, please discard the carrier and order a replacement product free of charge.

Actions – Commercial organization

- Send the combined Commercial organization initial and final report to Global QA, see page 4, as a confirmation that this information has been received.
- Send information as described in the Product Notification, PN2021-06, to your customer(s) that have received or may receive any of the affected lots of ImmunoCAP Total IgE, ImmunoCAP Specific IgE and ViewAllergy, see Appendix 1.

Actions – Manufacturing Site

- A CAPA, CA21-00048, has been opened to prevent this from occurring again.

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 and final report

ImmunoCAP Total IgE, ImmunoCAP Specific IgE and ViewAllergy.

- I hereby acknowledge that we have received this Quality Information, QI2021-06 and Product Notification, PN2021-06:

Yes

- Informed affected customer(s) about the content in the Product Notification, PN2021-06.

Yes

No

If No, reason:

- 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 and scanned copy to:

vigilance.idd@thermofisher.com



Appendix 1

Affected products

Allergen code	Material number	Lot number
d1	14-4107-22	AAXKC, AAXKG, AAXKH
d1	14-4107-01	357KE
f1	14-4111-01	361FA
f4	14-4113-01	363G8, 363G9
f13	14-4126-01	375P3, 375P4
f14	14-4115-01	364EH, 364EG
f92 VA	26-4334-22	DHJCY, DHJ CZ
f202	14-4835-01	997LV, 997LX, 997LY
f253	14-5093-10	699GW
f253	14-5093-01	BS3GW
f256	14-4521-01	CMEC3
fx3	14-4208-01	449BS
g2	14-4131-01	379CX, 379CW
g6	14-4100-01	350E1, 350E2, 350E3
g6 VA	26-4100-22	DT3B3
g10	14-4138-01	384C2
h1	14-4402-22	ACTDY, ACTDZ
i6	14-4224-01	465DK, 465DL
m2	14-4105-01	355DW, 355DY
m6	14-4106-01	356GF, 356GG
mx2	14-4320-01	851K1
mx2	14-4320-22	ADFK1
Sa-IgE	14-4417-01	865H4, 865H5
t2 VA	26-4146-22	DHACS
t3	14-4102-01	352DZ, 352E0, 352E1
t3 VA	26-4102-22	DHBDK
t7	14-4149-01	395DD, 395DE
t9	14-4150-01	396C3
t17	14-4118-22	ADSEE, ADSEF
Ta-IgE	14-4509-01	BJNUR, BJNUY, BJNUZ, BJNV1
Ta-IgE	14-4509-22	BGUUR, BGUIV1
w6 VA	26-4103-22	DGLDG



Document name Quality Information QA2021-06
Number 748916 Version 1.0

Issued by Ingela Eriksson 2021-Nov-25 15:37 CET

Reviewed by Lisa Rohbe 2021-Nov-26 08:12 CET
Reviewed by Malin Snetselaar 2021-Nov-25 15:39 CET

Approved by Fredrik Mirenborn 2021-Nov-26 09:26 CET
Release Date 2021-Nov-26 09:26 CET

