

Product Notification
ImmunoCAP Total IgE, ImmunoCAP Specific IgE and ViewAllergy

Dear Customer,

We want to inform you that an increased frequency of dispensing errors due to capsules stuck in carriers has been noticed during Q3 2021. Small deformations of capsules may occasionally occur during manufacturing. Unfortunately, it has been identified that one of the production equipment have been damaging 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, if this occurs it may lead to that the capsule cannot be dispensed in the Phadia instruments.

We are sorry for the inconvenience this is causing you.

If a dispensing error of this kind would occur in the Phadia instrument (P200, P250, P1000 and P2500/P5000)

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

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

- If a new ImmunoCAP carrier (for the same allergen) is available, this can be used, and the process continues accordingly.
- If no ImmunoCAP carrier (for the same allergen) is 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.

Affected products

Affected products, see Appendix 1



Actions to be taken:

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

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.

If this letter is being sent to a **Distributor** who will be conducting the correction in regard to its customers, use the following paragraph instead:

Our records indicate that you may have purchased one or more of the products in Appendix 1 for re-sale to your customers. Please contact your affected customer base, advise them of the situation, and provide them with a copy of this letter. In addition, qualified product support technicians will be available to address any questions about the affected product at:

Name

Address

Telephone

E-mail

We apologize for any inconvenience this may cause.
If you have any questions, please contact us.

Sincerely, _____

Name

ImmunoDiagnostics
Thermo Fisher Scientific

Address

Office; Mobile;

Email: **xxxxxx**@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, BGUV1
w6 VA	26-4103-22	DGLDG



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