
Urgent Field Safety Notice

Recall

concerning
EUROLINE Mediterranean Inhalation (IgE), order no.: DP 3112-1601 E, lots: A220706AI, A221208AB, A230322AH, A230516BO

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21 July 2023

From:
EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany
www.euroimmun.com

To:
Users and distributors

Identification of the medical/IVD products concerned:
EUROLINE Mediterranean Inhalation (IgE), order no.: DP 3112-1601 E, lots: A220706AI, A221208AB, A230322AH, A230516BO

Dear customers,

EUROIMMUN has initiated a field corrective action for the product specified above. This notification contains important information for your immediate attention.

Description of the problem and the determined cause:
The test kits of the above-mentioned lots may contain wrong test strips, which are coated with other allergens. The use of test kits with wrong test strips will lead to incorrect test results for the analysed patient samples if the error is not noticed by the user prior to testing.
The folded card with the test strips is labelled with the product name, allowing the user to identify it correctly and notice that it does not correspond to the test kit. Prior to performing the test, each test strip can also be identified by the printed product code.
If the folded card and the test strips have not been identified correctly, the test results may not be used, as these results may be false positive or false negative. Please repeat these tests and inform your customers.
The section “Limitations of in vitro allergy diagnostics” in the test instructions of the above-mentioned product contains the following note: “In any case, the final diagnosis should not be solely based on one type of analysis. A well-founded anamnesis and further laboratory findings should always be taken into account. Skin test as well as provocation test (if possible) are mandatory to receive the entire information needed for an optimal decision regarding the specific immunotherapy that should be applied. The clinical picture is not always in line with in vitro test results.”
The clinical diagnosis of an allergy is not based solely on the results of the in vitro determination of specific IgE antibodies, but must always take into account the detailed medical history as well as the results of further tests as part of a tiered allergy diagnostic approach (skin test, laboratory test, provocation). This means that false positive or false negative test results for specific IgE antibodies do not lead to an incorrect clinical diagnosis and have no therapeutic or health consequences.
There may be a delay in findings due to the need to repeat the testing.

No therapeutic or health consequences for the patient are to be expected in the case of delayed findings as there will already be a fundamental indication of the patient's allergy status based on other test methods and the availability of test results for specific IgE antibodies is not time-critical for treatment.

Measures to be taken:
Please make sure that any remaining stocks of the above-mentioned lots are no longer used in your laboratory and are disposed of. To prove that you have read this safety information, please send the completed reply form to the following fax number: +49 (0) 451 2032 100, or +49 (0) 451 5855 591 immediately, **latest until the 4th August, 2023.**

EUROIMMUN will replace the affected test kits in your stock free of charge. Please contact the allergy diagnostics product management of EUROIMMUN (allergy-pm@euroimmun.de).

Information to be passed on:
This notice must be forwarded to all users and distributors of the above-mentioned product.

Thank you for your cooperation! We apologise for any inconvenience this may cause.

For further information, please do not hesitate to contact EUROIMMUN using the information below.

Contact persons:

Product Management Allergy Diagnostics
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E-Mail: allergy-pm@euroimmun.de

PRRC-V Immunbiochemische Tests
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Signature / *Position PRRC-V*

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Please send back the customer reply as specified on the document!