



Link tot he SOP: [Meldungen von Vorkommnissen und Rueckruf von EUROIMMUN-Produkten](#)

Urgent Field Safety Notice

Recall

concerning

Anti-Saccharomyces cerevisiae-IIFT (IgA, IgG), Order no.: FV 2841-1010 A/G, FX 2841-1010,
Lot F200924CD, F210602VC

12 August 2021

Sender:

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

Recipient:

User and distributor

Identification of the medical/IVD products concerned:

Anti-Saccharomyces cerevisiae-IIFT (IgA), Order no.: FV 2841-1010 A, Lot: F200924CD, F210602VC;
Anti-Saccharomyces cerevisiae-IIFT (IgG), Order no.: FV 2841-1010 G, Lot: F200924CD, F210602VC;
Anti-Saccharomyces cerevisiae-IIFT, Order no.: FX 2841-1010, Lot: F200924CD; F210602VC

Dear customers,

The recall initiated by EUROIMMUN on 11th August 2021 has been extended to lot F210602VC. This letter contains important information for your immediate attention.

Description of the problem, incl. the determined cause:

Due to a production error, a total of 42 slides of the above mentioned product were produced without the antigen on the BIOCHIPS. These slides will therefore fail to show the required reaction in the presence of antibodies against *Saccharomyces cerevisiae* in a patient sample. Thus the positive control provided with the test kit will also show no reaction on the affected slides. As a result, the incubations must not be used to establish a diagnosis and the analyses must be repeated with a new test. Due to this, the interpretation of diagnostic findings may be delayed.

Measures to be taken:

Please ensure that any remaining stocks of the above-mentioned lot will no longer be used. In order to confirm that you have taken note of this safety information, please complete the form on page 3 and send it to the indicated fax number by 25th August 2021. For collection of the affected test kits we kindly ask you to contact us under +49 451 2032 9940 or order@euroimmun.de. EUROIMMUN will replace the kits free of charge.



Information to be passed on:

This notification must be forwarded to all users of the above-mentioned product. We apologise for any inconvenience caused and thank you for your support.

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

For further information, please do not hesitate to contact one of the following contact persons at EUROIMMUN.

Contact persons:

Product Management

Benjamin Dilberger

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Assigned Controller of Medical Devices

Immunofluorescence Diagnostics and

Molecular Genetic / Molecular Infection Diagnostics

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Assigned Controller of Medical Devices

Immunofluorescence Diagnostics and

Molecular Genetic / Molecular Infection Diagnostics

EUROIMMUN Medizinische Labordiagnostika AG

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Please send back the customer reply form to the mentioned addresses!