



Urgent Field Safety Notice

Assay programming "CXCL13"

Versions:

CXCL13

CXCL13 (V190913)

CXCL13 (V200324_01)

CXCL13 (V210114_02)

for automated processing on the EUROLabWorkstation

concerning

CXCL13 ELISA (test kit)

(Order No.: EQ 6811-9601-L)

1st November 2021

From:

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

To:

Users and distributors

Identification of the medical/IVD products concerned:

EUROLabWorkstation ELISA (Order No.: YG 0851-0101)

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:

During a review of the product CXCL13 ELISA on the EUROLabWorkstation ELISA, it was noticed that the needle washing steps after pipetting of CSF patient samples are insufficient at very high CXCL13 concentrations and may lead to carryover effects. Therefore, we cannot exclude the possibility of non-valid or false positive analysis results.

This is not a defect of the test kit CXCL13 ELISA.



Measures to be taken:

Until optimised assay programming is available, the CXCL13 ELISA must not be processed with the above assay versions on the EUROLabWorkstation. The test can still be performed manually or on the EUROIMMUN Analyzer I or I-2P.

We will provide you with a new assay programming as soon as possible.

CXCL13 is a non-specific inflammatory marker that can support the diagnosis in cases of suspected neuroborreliosis. Since a positive CXCL13 result must only be evaluated together with other findings and the clinical symptoms, a false positive analysis result alone does not represent a risk for the patient.

Information to be passed on:

This message must be forwarded to all users of the above product.

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

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

Contact persons:

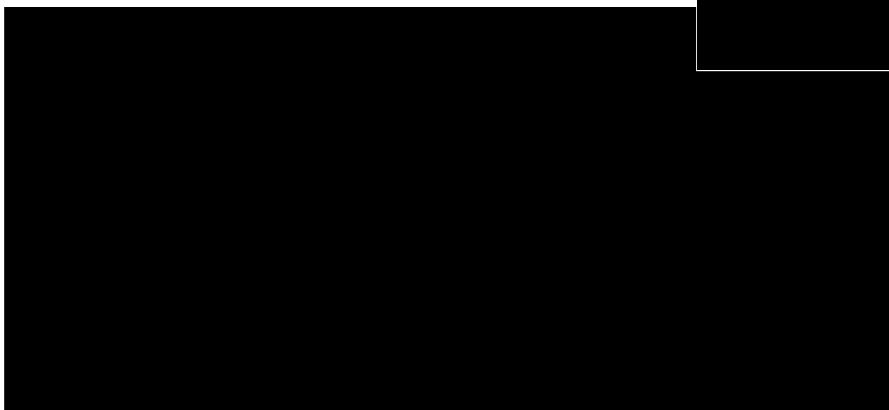
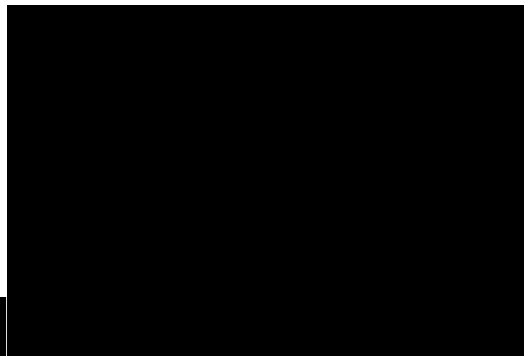
EUROIMMUN Help Desk

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Fax: +49 (0) 451 2032 7063

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Safety Officers:



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