
Urgent Field Safety Notice

Recall

concerning
Anti-IA2 ELISA (IgG), order no. EA 1023-9601 G, lot no. E220215BA

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3 June 2022

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

To:
Users and distributors

Identification of the medical/IVD products concerned:
Anti-IA2 ELISA (IgG), order no. EA 1023-9601 G, lot no. E220215BA

Dear Customer,

EUROIMMUN has initiated a field corrective action for the product Anti-IA2 ELISA (IgG), order no. EA 1023-9601 G, lot no. E220215BA. This notification contains important information for your immediate attention.

Description of the problem and determined cause:
Due to customer complaints in relation to invalid positive controls due to low optical density (OD) values for calibrator 3 during processing of the Anti-IA2 ELISA (IgG) (order no. EA 1023-9601 G) of lot E220215BA, we have initiated an investigation to confirm the existence of the problem, identify its cause and determine an appropriate corrective measure.

So far, the investigation has revealed that the calibrators 3 included in the aforementioned product lot might contain a concentration of IA2 antibodies that is too low, leading to a significantly reduced measurement signal (OD value) for calibrator 3 compared to the target value indicated on the quality control certificate valid for this lot.
The investigation also showed that this problem does not affect the other calibrators (1, 2, 4, 5, 6) and the controls included in the relevant test kit lot.

As a consequence of this significant measurement signal deviation for calibrator 3, the positive control contained in the test kit gives an invalid result. An invalid positive control indicates that the respective test processing and the results obtained for the analysed patient samples are invalid. It is possible that diagnoses are delayed due to these invalid test runs, but there is no risk of incorrect diagnosis.
If the calibration is valid, the positive control shows as valid and the test results can be used. Previous analyses of patient samples in which the affected lot was used and in which that was the case must therefore not be reanalysed.

Measures to be taken:
The fault encountered for calibrator 3 has no influence on the qualitative results of the test.
In the quantitative evaluation using the 450 nm calibration curve in accordance with the instructions for use, the faulty calibrator 3 has no negative influence on the quantitative results obtained for samples in the negative or weak positive concentration range. However, it will cause invalid results for the positive control included in the test kit and incorrect quantitative results for patient samples with a higher concentration if no evaluation method with automatic curve correction is used for the 405 nm calibration curve.

Please make sure that all remaining and potentially faulty calibrator 3 of the indicated lot are no longer used in your laboratory. We kindly ask that you fill in the template on page 3 to confirm that you have received this safety notice and that you send it by fax to the following number: +49 (0) 451 2032 7065 immediately, **latest until the 13th of June 2022.**

EUROIMMUN will replace the calibrator 3 free of charge. Please contact our colleague Anke Fletemeyer in the complaints department by email to a.fletemeyer@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 any of the following contact persons at EUROIMMUN.

Contact persons:

Product Management Endocrinology
Fax: +49 (0) 451 2032 7065
E-Mail: endocrinology-pm@euroimmun.de

PRRC-V Immunobiochemical Tests
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E-Mail: c.krueger@euroimmun.de

Signature / Person Responsible for Regulatory Compliance- Vigilance (PRRC-V)

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
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Please send back the distributor reply form as specified on the document!