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**Your reference**

**Our reference**

**Date**
02/02/2022



# Urgent Field Safety Notice (reply required, please refer to page 4)

## Corrective Action: Recall of *recom*Scan Version 3.4, Build-Versions below 166

**Product:**

Product 1:
Art. no. 31006
Name of product (de/en): *recom*Scan Vollversion / *recom*Scan full version
Version: 3.4
Build: < 166

Product 2:
Art. no. 31013
Name of product (de/en): *recom*Scan Upgrade / *recom*Scan Upgrade
Version: 3.4
Build: < 166

**Potentially inaccurate report of data by *recom*Scan software.**
Affected test systems:

- *recom*Line EBV IgG [Avidität] [IgA] (Article no. 4572 / 4576)
- *recom*Line Parvovirus B19 IgG [Avidität] (Article no. 4472)
- *recom*Line CMV IgG [Avidität] (Article no. 5572)
- *recom*Line Toxoplasma IgG [Avidität] (Article no. 5972)

Dear Customer and Partner,

With this letter we would like to inform you about a defective version of *recom*Scan 3.4 software for avidity test systems.

When evaluating the avidity tests listed above, inaccurate data transmission by the *recom*Scan 3.4 software only occurs under the following conditions:

1. premise: the order of strips of an avidity testing is resorted by the software using the sorting function (click on the left within the table header), so that the order of the strips is no longer identical to the scan.
2. premise: after sorting of strips in the software an export of data into a laboratory information system (LIS) is performed.

**When sorting the strips in the software, the result column and the antigen column are always correct**! If the position of the IgG strips is changed by sorting the strips, the index value of the antigens of the avidity strips in the %CO-column and in the R-column of the specific antigens will no longer match the original analysis.

Avidity testing allows differentiation of the stage of infection. Incorrect division as an acute or past infection may lead to overtreatment, failure or delay of therapy, or result in an incorrect differential diagnosis. In the case of examinations during pregnancy (concerns the parameters Parvovirus B19, CMV and Toxoplasma), this can have a corresponding effect on the health of the unborn child. However, it must be assumed that a therapeutic decision is not based solely on the results of a single laboratory diagnostic detection test, but that the clinical findings always serve as the basis, supported by laboratory diagnostics. An incorrect differentiation of the stage of infection due to the described software error (incorrectly assignment of the specific avidity indices to the respective IgG strip) is extremely unlikely, as the overall result and the listing of the antigen indices are always correct. So far, we are not aware of any cases in which the software error has led to a risk for patients. Nevertheless, it cannot be ruled out that there may be clinical consequences for the subject in individual cases.

The source of the error in the software was identified and corrected by the software manufacturer, BioSciTec GmbH.

The software version *recom*Scan 3.4 Build 166 does not contain the error and will provide accurate results even under the terms mentioned above.

**Recommendations for the user:**

You are using the *recom*Scan version 3.4 to evaluate avidity strips, resort the strips in the analysis and export the results afterwards to your LIMS system

- Please do not use the sorting function any more until further notice!
- Our technical support will contact you and provide the current *recom*Scan version free of charge as soon as possible. Tel. +49 89 54801-139, E-mail: tech.support@mikrogen.de
- Please ensure that this notice will be passed to all staff members within your organization and to all of your customers affected.

We kindly ask you to confirm the receipt of this letter by returning the reply form on page 4 by E-mail to vigilance@mikrogen.de or by fax +49 89 54801-100 until 16-02-2022.

Mikrogen apologizes for any inconvenience caused. For any further questions please feel free to contact us.

Sincerely,

J. Schamberger

Julia Schamberger
Safety representative for medical devices

## Reply for Distributors to Field Safety Notice

**Please return this reply until 16-02-2022 to: vigilance@mikrogen.de or fax +49 89 54801-100**

With your signature you acknowledge that you have received, read, and understood the included Urgent Field Safety Notice regarding the recall of *recom*Scan version 3.4, build versions lower than 166.

You further confirm that you are implementing all recommended actions as indicated.

Name _____

Position _____

Company _____

Street _____

Postal Cody/City _____

Date and Signature _____