MIKROGEN
DIAGNOSTIK

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Ansprechpartner
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Ihre Zeichen

Unsere Zeichen

Datum
Neuried, 19.04.2023

Field Safety Notice (reply required, please refer to page 3)

Product: ***DSX „.asy"-files for processing of recom*Well *assays in DSX devices***

Corrective action: Missing validation criterion for double analysis of cut-off control in ".asy"-files for DSX devices

Dear Partner,
we have to inform you, that a potential gap in validation of *recom*Well tests using the DSX device has been identified by our internal quality management. For some of the ".asy"-files used for processing *recom*Well tests on the DSX device, one validation criterion was missing:

"The single extinction values of the double analysis of the cut-off control do not deviate more than 20 % from their average."

In cases where this criterion is not met, there could be a potential risk for false results. The monitoring of single extinction values of the cut-off control in combination with further validation criteria found in the *Instructions For Use* serves to increase reliability of the processing of our *recom*Well tests.

*Recom*Well tests are mostly used as screening tests for diagnostics of infectious diseases, which is why they may have limited significance as a single test. In cases where *recom*Well tests are used for other diagnostic applications (e.g. clarification or confirmation of search tests), other tests results contribute to the final finding. In general, according to current guidelines, the results of each test should be considered in the context of the clinical picture and further investigations.

Action Recommendations for you as a distribution partner:

We kindly ask you to identify customers using the DSX for processing of *recom*Well Assays with ".asy"-Assay files missing the cut-off control validation and provide them with your FSN regarding this topic. Files with this gap in validation have to be corrected.
Of course, we are happy to assist with the correction, please contact us at vigilance@mikrogen.de which *recom*Well assays are processed on the DSX by your customers and we can provide you with updated files.

According to current knowledge, you can assume that there is no need for action with regard to historical data.

Please ensure in your customer's organisation that all users of the above-mentioned software and other persons to be informed are made aware of this safety information.
The Federal Institute for Drugs and Medical Devices (BfArM) has been informed about this measure.

We kindly ask you to notify us of the receipt of this safety information by email to vigilance@mikrogen.de or by fax to +49 89-54801-100 at the latest 30.06.2023. You will find the reply on page 3 of this letter.

Mikrogen sincerely apologizes for any inconvenience caused to you and your customer and thanks you for your response.
Should you have any questions regarding this action, please do not hesitate to contact us at any time.

Yours sincerely,

[redacted]

Eva Staschik
(Vigilance)

Reply for Distributors to Field Safety Notice

*DSX „.asy“-files for processing of recom*Well *assays in DSX devices*

Please return this reply until 30-06-2023 to: vigilance@mikrogen.de or fax +49 89 54801-100

1.) I have read the letter and taken note of it. □ Yes □ No

2.) I have sent my affected customers an FSN regarding the topic and ensured the check and, if needed, correction, of affected files. □ Yes □ No

(If no, please give reasons:)

Name _____

Position _____

Company _____

Street _____

ZIP code / City _____

Date and Signature _____