MIKROGEN
DIAGNOSTIK

MIKROGEN GmbH |

Contact

Date
, 29.11.2023

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Urgent safety information

(reply required, page 3)

due to a programming gap in the interpreter *recom*Line HIV-1 & HIV-2

Product: *recom*Line HIV Rev001 Build001.stc and *recom*Line HIV Rev001 Build002.stc

Subject: Programming gap with an extremely rare band ratio of gp41 to gp36, resulting in a "borderline" output instead of "positive, non-typeable".

Dear Partner,

in the course of continuous quality monitoring, a gap was recognised in the programming of the HIV interpreter during computer-aided evaluation using *recom*Scan 3.4.
We would like to emphasise that our product *recom*Line HIV-1 & HIV-2 (article number 6672) is not affected by this issue and can be used without hesitation.

This gap in the programming of *recom*Scan can occur in extremely rare cases with the software-supported differentiation of the HIV-positive *recom*Line HIV-1 & HIV-2 strips. For the differentiation of HIV-positive strips, the quotient of the intensities (grey levels) of the two antigens gp41 to gp36 is considered:

- Quotient gp41/gp36 > 1.5: a positive HIV-1 result is output in *recom*Scan
- Quotient gp41/gp36 <= 0.75: a positive HIV-2 result is output in *recom*Scan
- Quotient gp41/gp36 < 1.5 and >=0.75: it is output in *recom*Scan as positive, non-typeable
- Quotient gp41/gp36 = 1.5: this is missing in the programming; no result is therefore stored in recomScan for this quotient. In this case, a borderline result for the patient sample is output as the basic result.

This means that a borderline result is only issued via *recom*Scan HIV-1 & HIV-2 in the extremely rare case, that the quotient of the grey levels of the two antigens gp41 to gp36 is precisely 1.50, although the corresponding strip is clearly recognisable as positive.

HIV-1 & HIV-2 are categorised as high-risk parameters. In this case, the risk for the patient can be assessed as low, as a borderline result will result in further tests (see instructions for use, chapter 10).
Furthermore, the *recom*Scan software is intended to support the interpretation of the test strips and the original strips must always be taken into consideration when interpreting the results (see instructions for use, chapter 9.2).

Recommended action for your *recom*Scan customer:

- According to the current state of knowledge, you can assume that there is no need for action with regard to historical data.
- As usual, you can analyse the *recom*Line HIV-1 & HIV-2 strips via *recom*Scan, including the original strips.
- We ask you to exchange the interpreter for *recom*Line HIV-1 & HIV-2. Proceed as described in the attachment "Replacement *recom*Scan Interpreter":

Please ensure that all customers who work with the above-mentioned product are informed of this safety information. Once the *recom*Line HIV interpreter has been replaced, the measure is complete. All *recom*Scan interpreters for HIV purchased from us from 27 November 2023 have been corrected and are not affected by this field safety corrective action.
The Paul-Ehrlich-Institut has been informed about this measure.

Please confirm receipt of this safety information by completing the reply form on page 3. You can send us this reply by e-mail to vigilance@mikrogen.de or by fax to +49 (0) 89-54801-102. We kindly ask you to reply by 31.12.2023.

We sincerely apologise for any inconvenience caused and thank you for your support.

If you have any questions about this measure, please do not hesitate to contact us at any time.

With kind regards,

Vigilance
MIKROGEN GmbH

Response from the distribution partner to the safety information
*recom*Line HIV-1 & HIV-2

We kindly ask you to send us this reply by e-mail to vigilance@mikrogen.de or by fax to +49 (0) 89-54801-102. Please respond by 31.12.2023. Thank you!

1. I have read and taken note of the recommended measures □ **Yes** □ **No**

2. I have forwarded the recommended measures to my *recom*Scan customers.
   My *recom*Scan customers are located in the following countries (see below) □ **Yes** □ **No**

3. I have removed the faulty interpreter *recom*Line HIV-1 & HIV-2 Rev001 Build001
   and/or Build002 from my *recom*Scan customers and replaced it with the
   corrected interpreter *recom*Line HIV-1 & HIV-2 Rev001 Build003. □ **Yes** □ **No**

If no, please give reasons:

affected countries:

Name

Position

Company

Street / Number

Postcode/location

Date and signature