

Urgent safety information

(reply required, page 3)

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

Product: *recomLine* HIV Rev001 Build001.stc and *recomLine* 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 *recomScan* 3.4.

We would like to emphasise that our product *recomLine* 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 *recomScan* can occur in extremely rare cases with the software-supported differentiation of the HIV-positive *recomLine* 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 *recomScan*
- Quotient $gp41/gp36 \leq 0.75$: a positive HIV-2 result is output in *recomScan*
- Quotient $gp41/gp36 < 1.5$ and ≥ 0.75 : it is output in *recomScan* 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 *recomScan* 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 *recomScan* 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 *recomScan* 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 *recomLine* HIV-1 & HIV-2 strips via *recomScan*, including the original strips.
- We ask you to exchange the interpreter for *recomLine* HIV-1 & HIV-2. Proceed as described in the attachment "Replacement *recomScan* Interpreter":

Please ensure that all customers who work with the above-mentioned product are informed of this safety information. Once the *recomLine* HIV interpreter has been replaced, the measure is complete. All *recomScan* 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,

Martina Wild

Vigilance
MIKROGEN GmbH

Response from the distribution partner to the safety information *recomLine 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 *recomScan* customers.
My *recomScan* customers are located in the following countries (see below) ☐ Yes ☐ No

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

If no, please give reasons:

affected countries:

Name

Position

Company

Street / Number

Postcode/location

Date and signature

Vorgehen Austausch der betroffenen *recomScan* HIV-1 & HIV-2 Interpreter:

Den korrigierten Interpreter ***recomLine* HIV-1 & HIV-2 Rev001 Build003** können Sie oder Ihre *recomScan* Kunden von der Homepage über folgenden Link herunterladen:

<https://cloud.mikrogen.de:8443/index.php/s/auL8JmBxTlpMBXU>

- 1.) Bitte kopieren Sie die Datei *recomLine* HIV-1 & HIV-2 Rev001 Build003 auf einen freien USB Stick.
- 2.) Öffnen Sie in Ihrem Rechner, auf dem *recomScan* installiert ist, den Windows Explorer (rechte Maustaste auf dem Windows-Startknopf -> Explorer) und kopieren sie folgenden Link in den Dateipfad:
C:\ProgramData\recomScan\Company\Mikrogen\Test
Drücken Sie "Enter" zum Öffnen des Pfades.
- 3.) Löschen Sie den Interpreter *recomLine* HIV-1 & HIV-2 Rev001 Build001 und/oder Build002.
- 4.) Kopieren Sie den neuen Interpreter aus dem Link (auf Ihrem USB-Stick) und legen Sie diesen in den Ordner aus Punkt 1.
- 5.) Schließen Sie den Ordner.
- 6.) Der neue Interpreter sollte nun wie gewohnt verwendet werden können.

Hinweis:

Der Interpreter ist von Mikrogen GmbH in der CutOff Index Version voreingestellt. Falls Sie oder Ihr Kunde eine andere Einstellung benötigen oder sonstige Fragen zur technischen Umsetzung haben, wenden Sie sich bitte an Ihren Distributionspartner. Dieser wird umgehend mit Mikrogen in Kontakt treten.