

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

Product: *recomLine* HTLV-1 & HTLV-2 IgG, Article no. 5272

Batch No.: LHT072101

Subject: reduced stability of use after first use of the kit

Dear Partner,

after evaluating our real-time stability data of our *recomLine* HTLV-1 & HTLV-2 IgG product, we have determined that the stability in use must be limited to nine months after the kit has been opened.

The total shelf life of the kit is twelve months. This is indicated on the kits.

Accordingly, the allowable duration of use after the kit has been opened the first time may be less than the total shelf life of the kit.

A corresponding note on the duration of use after the first opening will be included in the instructions for use of the kit in the future. This will bear the version number GARLHT003.

Based on our shipping records, we were able to accurately identify the directly affected customers.

Your customer is directly affected, when they have received our *recomLine* HTLV-1 & HTLV-2 IgG of lot LHT072101 **before** 01.10.2021

We will additionally inform you by phone if one of your customers is directly affected by the issue!

However, your customers are not affected, when they have received our *recomLine* HTLV-1 & HTLV-2 IgG of lot LHT072101 **from** 01.10.2021. **These kits can be used without further restriction until the end of the shelf life.**

If designated kits are used nine months after initial use, there may be a possibility of false positive or false borderline results.

Nevertheless, the risk for the patient is low, because the *recomLine* HTLV-1 & HTLV-2 IgG as a confirmation test is mostly part of a stepwise diagnostic.

Action Recommendations for directly affected customers:

- Please quarantine the affected kits and do not use them from now on
- Please inform us how many kits you have quarantined
- As soon as the new batch is available, we will contact you again

In distinction, the soon-to-be-available new batch comes with revised instructions for use (GARLHT003) and is not affected by this safety information.

Please ensure, that all your customers working with the product are informed about this Field Safety Notice accordingly. We kindly ask you to confirm receipt of this letter by returning the reply form on page 3 by e-mail to **vigilance@mikrogen.de** or by **fax +49 89 54801-100** until **18.03.2022**.

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

Sincerely,



Martina Wild
Deputy Safety Representative of Medical Devices

Reply for Distributors to Field Safety Notice

Please fill in and return until **18.03.2022** to: vigilance@mikrogen.de or
Fax **+49 89-54801-100**

Confirm of receipt of Field Safety Notice from 28.02.2022 regarding the product
recomLine HTLV-1 & HTLV-2 IgG of lot LHT072101.

1. I have read and understood the recommendations Yes No
2. Our Customers are directly affected by the Field Safety Notice and have put the following number of kits of *recomLine* HTLV-1 & HTLV-2 IgG in quarantine Yes No

Name

Position

Company

Street

Postal Code/City

Date and Signature
