

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

Product: *recomLine SARS-CoV-2 IgG [Avidity] Batch LCS062003 (RUO)*

Subject: **Misprint on outer kit box label; Test performance not affected**

Dear Customer and Partner,

Herewith we are informing you about a misprint on the outer kit box label of our product **recomLine SARS-CoV-2 IgG [Avidity] of the batch LCS062003**. The affected batch has been released to the market under the diagnostic demand of the Covid-19 pandemic as RUO (research use only) batch. Accidentally, a part of this batch has additionally to the RUO sign, also the CE sign printed on the outer kit box label.

Affected test kits have been sent out between **July, 23rd to August, 12th**, only. Test kits of the same batch before or after this delivery date are not affected. According to our documentation you have received affected test kits within the described delivery time frame.

The test performance of the test kits is not affected by the misprint in any way. Only the outer kit box labels are affected by the misprint. All kit components inside the test kit are correctly labelled as RUO. Affected test kits can be used without any limitation according to RUO labelling. There is no requirement for affected test kits to be destroyed or sent back to manufacturer or to your local distributor.

To avoid confusion: the new batch LCS082001, available since 20.08.2020 with valid CE labelling, is not affected by this Field Safety Notice.

We kindly ask you to please confirm receipt of this Field Safety Notice to vigilance@mikrogen.de.

Within the scope of manufacturers vigilance, Mikrogen is going to report this field safety notice to the German National Competent Authority (BfArM). You will find the reply on page 3 of the attached letter.

Mikrogen apologizes for any inconvenience caused.

For any further questions please feel free to contact us.

Sincerely,

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MIKROGEN GmbH | Floriansbogen 2-4 | 82061 Neuried

**Reply for Distributors to Field Safety Notice
recomLine SARS-CoV-2 batch LCS062003 (RUO)**

Please return this reply to: vigilance@mikrogen.de until September 11th, 2020.

1. I have read and understood the recommendations. Yes No
2. I informed all staff members of my enterprise
working with the product. Yes No

Name

Position

Company

Street

Postal Cody/City

Date and Signature
