

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

Product: *ampliCube* Coronavirus SARS-CoV-2, Art. No. 50143
Batch No.: ACVS042004

Subject: Empty tubes of the Internal Control (Batch No.: RVIC042003)

Dear Customer and Partner,

According to our manufacturing records you have been supplied with our test kit *ampliCube* Coronavirus SARS-CoV-2 of batch number ACVS042004.

Our quality control and customer feedback management revealed that some test kits of the above mentioned batch contains internal control tubes that have not been filled. If you are concerned, please follow the steps, described below:

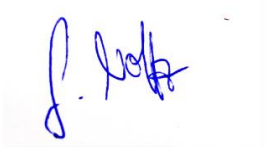
- Please put the batch in quarantine and send it back to your distributor or destroy the kit.
- Please let us know the number of affected test kits in your stock, by sending back the attached reply form (page 3). Those test kits will be replaced free of charge.

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

Mikrogen apologizes for any inconvenience caused.

For any further questions please feel free to contact us.

Sincerely,



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Dr. Gabriele Noffz
Deputy Safety representative for medical devices

MIKROGEN GmbH | Floriansbogen 2-4 | 82061 Neuried

**Reply for Distributors to Field Safety Notice
ampliCube Coronavirus SARS-CoV-2 batch ACVS042004**

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

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|----|--|------------------------------|-----------------------------|
| 1. | I have read and understood the recommendations | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. | I informed all staff members of my enterprise working with the product. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. | I stopped using the affected products and I put all respective products on stock in quarantine | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Confirmation	
Product description, batch number	Number of products affected

Name _____

Position _____

Company _____

Street _____

Postal Cody/City _____

Date and Signature _____