MIKROGEN GmbH | Anna-Sigmund-Str. 10 | 82061 Neuried | Germany

Contact
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date
Neuried, 19.03.2026

Urgent safety information
(reply required, page 3)
due to possible false-negative results for influenza A virus

Products:
***ampli*Cube Respiratory Viral Panel 5 (article-no. 50152)**
***ampli*Cube Respiratory Flu & SARS-CoV-2 (article-no. 50163, 50164)**
***ampli*Cube Respiratory Flu & SARS-CoV-2 LC (article-no. 50173, 50174)**

Subject: Mutations in the Influenza A virus (H1N1) pdm09 subtype may lead to false-negative results.

Dear Partner,

during the current 2025/26 season of acute respiratory infections, an influenza A virus (H1N1) pdm09 variant is circulating in the field carrying mutations in the target region used for the detection of influenza A virus. These mutations may affect the binding affinity of the primers used in the influenza A virus channel. Depending on the sampling and extraction efficiency, this may lead to a false-negative result in patient samples with a low viral load.

We would like to emphasise that our product *ampli*Cube Respiratory Viral Panel 1 (article-no. 50102) is not affected by this issue, as the mutated variant of the subtype continues to be detected via the H1N1 channel.

Recommendations for you as a partner and your customers:

- Based on current knowledge, you and your customers can assume that no action is required with regards to historical data. Test results must always be considered in conjunction with the clinical picture. In recent cases, retesting may be considered for high-risk patients, e.g. those at risk of Reye's syndrome, at the discretion of the treating physician.

- Please inform us of your stock as well as your customers stock of the above-mentioned products. We will replace these accordingly:
  - o *ampli*Cube Respiratory Viral Panel 5 with *ampli*Cube Respiratory Viral Panel 1 (article-no. 50102) and *ampli*Cube Respiratory Viral Panel 3 (article-no. 50122).
  - o *ampli*Cube Respiratory Flu & SARS-CoV-2 (LC) for *ampli*Cube Respiratory Viral Panel 1 (article-no. 50102) and *ampli*Cube Coronavirus SARS-CoV-2 (article-no. 50143)
- Please destroy any kits of the above-mentioned products currently in your stock. Please ensure that your customers also destroy all affected kits in stock.

Please ensure that all customers working with the above-mentioned product are made aware of this safety information. As part of this measure, the products will be updated and made available as soon as possible.

The BfArM has been informed of this measure.

We ask you to confirm receipt of this safety information by completing the reply form on page 3. You can send this reply to us by email to vigilance@mikrogen.de or by fax to +49-89-54801-100. We kindly ask for your answer by 30th April 2026.

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

Should you have any questions regarding this measure, please do not hesitate to contact us.

Kind regards,

Vigilance

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Bankverbindung
IBAN: DE18 7015 0000 0108 1272 00
BIC/SWIFT: SSKMDEMM
Stadtsparkasse München

Account for payments in US Dollar:
IBAN: DE43 7015 0000 0890 0011 67
BIC/SWIFT: SSKMDEMM
Bank: Stadtsparkasse München

Geschäftsführer: Dr. Erwin Soutschek, Gerald Linden
Sitz der Gesellschaft: Neuried (München)
Reg.-Gericht: München H RB Nr. 87312
USt.-Nr. Mikrogen GmbH: DE125416542

Response from the distribution partner regarding the safety information for

***ampli*Cube Respiratory Viral Panel 5 (article-no. 50152)**
***ampli*Cube Respiratory Flu & SARS-CoV-2 (article-no. 50163, 50164)**
***ampli*Cube Respiratory Flu & SARS-CoV-2 LC (article-no. 50173, 50174)**

We kindly ask you to send us your response by email to vigilance@mikrogen.de or by fax to +49-89-54801-100. We would appreciate your response by 30 April 2026. Thank you very much!

1. I have read and taken note of the recommended measures.	☐ **yes** ☐ **no**
2. I have forwarded the recommended measures to my affected customers and received feedback regarding kit numbers.	☐ **yes** ☐ **no**
2. Number of kits (in your stock and in your customers' stock):	
*ampli*Cube Respiratory Viral Panel 5	
*ampli*Cube Respiratory Flu & SARS-CoV-2	
*ampli*Cube Respiratory Flu & SARS-CoV-2 LC	
3. I confirm that the kits listed above have been properly disposed of.	☐ **yes** ☐ **no**

We will contact you with further details regarding the dispatch of the replacement kits.

If no, or if you do not wish an exchange, please explain why:

Please specify the countries to which the affected kits were distributed:

Name

Position

Company

Street/Number

Postcode/location

Date and signature

Account for payments in US Dollar: