

August 23, 2021

## Urgent Field Safety Notice

QIAstat-Dx<sup>®</sup> Respiratory SARS-CoV-2 Panel (Cat. no. 691214, LOT 210054)

Dear QIAstat-Dx customer,

This Urgent Field Safety Notice is to inform you that QIAGEN has identified sixteen (16) faulty cartridges in LOT 210054 of the QIAstat-Dx Respiratory SARS-CoV-2 Panel, cat. no. 691214.

According to our records, you have received at least one kit from the affected product LOT.

For the 16 affected cartridges, the reaction chambers contain incorrect primer–probe mixes. The serial numbers (SN) of the 16 affected cartridges are listed on Table 1 below. If an affected cartridge is used, several possibilities for false-negative, false-positive, or a combination of both false-negative and false-positive results could occur. Targets that could potentially be affected with incorrect results include Influenza A, Influenza A H1N1 pdm09, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Adenovirus, Respiratory Syncytial virus A+B, Human metapneumovirus A+B, Bocavirus, and SARS-CoV-2.

**Table 1. List of Affected Serial Numbers (SN)**

410541336	410541346
410541337	410541347
410541338	410541348
410541339	410541349
410541340	410541350
410541342	410541351
410541343	410541352
410541344	410541356

### Potential risks associated with the issue:

False results could lead to incorrect treatment decisions that could set off adverse events linked to the nature of the treatment (i.e., use of antibiotics/antivirals). A false-positive diagnosis also has the potential to delay or miss the correct differential diagnosis, thus delaying initiation of appropriate treatment.

Additionally, false-negative results have the potential to delay differential diagnosis, thus delaying initiation of appropriate treatment.

**Actions to be taken by the customer/user:**

- Please check the cartridge SNs received from LOT 210054 against the list of affected cartridges shown in Table 1 (page 1). If you have received one of the affected cartridges, please contact QIAGEN Technical Service for a free-of-charge replacement.
- If you have received one of the 16 affected cartridges and have not used it, please dispose of it immediately in accordance with your national and local safety and environmental regulations.
- If you already used one of the affected cartridges from this LOT, please identify the results obtained with the affected SN listed on Table 1 (page 1). For results obtained with an affected SN, review the results as follows:
  - Review all results of the respective targets mentioned on page 1 to exclude erroneous diagnosis and treatment, except in those cases where alternative confirmation was obtained.
  - Review any result for which tests were performed on clinical and/or epidemiological suspicion of the respective targets.
- If you have remaining stocks from LOT 210054, cat. no 691214 with cartridge SNs not found in the list, you may still use these cartridges, as this issue is limited to the 16 cartridges listed on Table 1 (page 1).
- Review this notice with your laboratory/medical director.
- **IMPORTANT:** Forward this information to all individuals and departments within your organization using the above listed kits. If you are not the end user, please forward this notice to the product end user.
- Complete the Acknowledgement of Receipt attached to this letter by Sept. 06, 2021.
- Commercial partners:
  - Cease distribution of the product listed in this notice
  - Forward this notice to your customers
  - Follow-up on the Acknowledgements of Receipt with your customers

**Actions taken by QIAGEN:**

As part of our Quality Assurance process, we are investigating this incident and are implementing corrective actions.

If you have any questions or concerns, please contact your local QIAGEN Technical Service Department through any of the following:

QIAGEN Subsidiaries

<https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/>

QIAGEN Commercial Partners and Importers

<https://www.qiagen.com/about-us/contact/global-contacts/distributors-and-importers/>

We sincerely apologize for any inconvenience this may cause and thank you in advance for your cooperation.

Sincerely,

**Your QIAGEN Team**

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### Acknowledgment of Receipt Form

Please complete this form and reply via email to [quality.communications@qiagen.com](mailto:quality.communications@qiagen.com) by Sept. 06, 2021, using the following acknowledgment text (it will be equivalent to your signature):

I hereby acknowledge that I have received, read, and understood the included Urgent Field Safety Notice 'QIAstat-Dx Respiratory SARS-CoV-2 Panel, cat. no. 691214, LOT 210054, dated August 23, 2021. We have taken the necessary actions as suggested by this notice.

We acknowledge that this document may be presented to regulatory or administrative bodies globally according to mandatory legislation.

**Laboratory name:**

**Address:**

**Contact name:**

**Title:**

**Email address:**

**Phone number:**

**Date:**

**Signature:**