

Dec 30, 2020

## Urgent Field Safety Notice

QIAstat-Dx Respiratory SARS-CoV-2 Panel REF 691214  
LOT 200218

Dear QIAstat-Dx customer,

This Urgent Field Safety Notice is to inform you that QIAGEN has discovered faulty cartridges in LOT 200218 of the QIAstat-Dx Respiratory SARS-CoV-2 Panel, REF 691214.

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

In some cartridges, the reaction chamber that should hold the reaction mix for the SARS-CoV-2 target falsely contains the mix for atypical bacteria targets *Mycoplasma pneumoniae*, *Legionella pneumophila*, and *Bordetella pertussis*, and vice versa. The serial numbers (SN) of affected cartridges are listed in the table on the last page of this letter (page 5).

Our investigation concluded that the following result scenarios are possible if an affected cartridge is used:

- (A) SARS-CoV-2 false negative with simultaneous *Mycoplasma pneumoniae* false positive result.
- (B) SARS-CoV-2 false positive with simultaneous *Mycoplasma pneumoniae* false negative result.
- (C) *Legionella pneumophila* false negative result.\*
- (D) *Bordetella pertussis* false negative result.\*

\* *Legionella pneumophila*, and *Bordetella pertussis* targets do not share the same detection dye with the SARS-CoV-2 target and thus cannot give a false positive result in the SARS-CoV-2 reaction chamber. Consequently, only a potential false negative scenario is possible for these two targets if an affected cartridge is used.

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**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:**

- If you have remaining stock of LOT 200218, REF 691214, **do not use it**. Please contact QIAGEN Technical Service for a free-of-charge replacement.
- Dispose of the product LOT 200218 in accordance with your national and local safety and environmental regulations.
- If you already used cartridges from this LOT, please identify the results obtained with the affected SN listed on the last page of this letter (page 5). Cartridge serial numbers are recorded in the test details section of the results report. For results obtained with an affected SN, review the results as follows:
  - Review all *Mycoplasma pneumoniae* positive results to exclude erroneous diagnosis and treatment, except in those cases where alternative confirmation was obtained.
  - Review all SARS-CoV-2 positive results to exclude erroneous diagnosis and treatment, except in those cases where alternative confirmation was obtained.
  - Review any negative result for which tests were performed on clinical and/or epidemiological suspicion of *Bordetella pertussis* or *Legionella pneumophila*.
- 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 Acknowledgement of Receipt attached to this letter by Jan 15, 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

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**Actions taken by QIAGEN:**

All affected material in stock has been blocked. As part of our quality control process, we are investigating this and are implementing corrective actions.

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

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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QIAstat-Dx Respiratory SARS-CoV-2 Panel REF 691214 LOT 200218

### Acknowledgment of Receipt Form

Please complete this form and reply via email to [quality.communications@qiagen.com](mailto:quality.communications@qiagen.com) by Jan 15, 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 REF 691214 LOT 200218, dated Dec 30, 2020. 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:**

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200218

### List of affected serial numbers (SN)

402180003	402180074	402180152	402180225
402180005	402180077	402180154	402180227
402180007	402180079	402180156	402180229
402180008	402180082	402180158	402180231
402180011	402180083	402180160	402180234
402180013	402180086	402180162	402180236
402180016	402180088	402180164	402180238
402180018	402180091	402180166	402180240
402180019	402180092	402180167	402180242
402180020	402180094	402180169	402180244
402180023	402180096	402180171	402180246
402180025	402180097	402180174	402180248
402180027	402180099	402180176	402180251
402180029	402180103	402180179	402180253
402180031	402180105	402180181	402180256
402180033	402180107	402180183	402180258
402180035	402180108	402180185	402180259
402180037	402180109	402180187	402180262
402180039	402180111	402180189	402180264
402180041	402180114	402180191	402180266
402180044	402180116	402180193	402180268
402180045	402180118	402180195	402180270
402180047	402180120	402180198	402180272
402180049	402180122	402180199	402180273
402180051	402180124	402180201	402180276
402180053	402180126	402180203	402180278
402180055	402180128	402180205	402180279
402180057	402180130	402180207	402180282
402180059	402180132	402180209	402180284
402180061	402180134	402180211	402180286
402180063	402180137	402180213	402180288
402180065	402180139	402180214	402180290
402180066	402180141	402180217	402180293
402180070	402180143	402180219	402180295
402180071	402180147	402180221	402180297
402180072	402180150	402180223	402180299