

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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### 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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QIAstat-Dx Respiratory SARS-CoV-2 Panel REF 691214 LOT 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 |