April 2023

Urgent Field Safety Notice

QIAstat-Dx® Gastrointestinal Panel REF 691411
LOTS 220218 and 220224

Dear QIAstat-Dx customer,

This Urgent Field Safety Notice is to inform you that QIAGEN has discovered a malfunction on cartridges of LOTS 220218 and 220224 of the QIAstat-Dx Gastrointestinal Panel, REF 691411.

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

Cartridges of LOTS 220218 and 220224 do have a defect that would not allow detection of Shiga-like toxin producing E. coli (STEC) that carries a less common subtype of the *stx2* gene (stx2f). Samples containing STEC carrying the *stx2f* variant would be called as negative for STEC. It is expected that most, but not all samples would be instead called positive for EPEC. This defect is not affecting detection of all other claimed subtypes of STEC or other targets within the panel in any way.

Potential risks associated with the issue:

False negative results for STEC subtype *stx2f* could drive into a wrong diagnosis. This could lead to wrong treatment (usage of antibiotics used for severe cases of EPEC when this is not indicated for STEC subtypes).

Actions to be taken by the customer/user:

- If you have remaining stock of LOTS 220218 and/or 220224, REF 691411, **do not use it**. Please contact QIAGEN Technical Service for a free-of-charge replacement.
- Dispose of the product LOTS 220218 and 220224 in accordance with your national and local safety and environmental regulations.
- If you already used cartridges from these LOTS, please reevaluate severe cases reported as EPEC when tested with listed lots for potential STEC subtype *stx2f* cases for epidemiology reporting purposes.
- Review this notice with your laboratory/medical director.

- IMPORTANT: Forward this information to all individuals and departments within your organization using the above-listed LOTS. 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 April 30, 2023.
- 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:

All affected material in stock has been blocked. This defect has been identified as related to primers and probes supply and testing and has already been properly investigated and appropriate corrective actions are in place to avoid recurrence.

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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LOTS 220218 and 220224

Acknowledgment of Receipt Form

Please complete this form and reply via email to **quality.communications@qiagen.com** by April 30, 2023, 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 Gastrointestinal Panel REF 691411 LOTS 220218 and 220224, dated April 3, 2023. 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: