February 2026

Urgent Field Safety Notice

QIAstat-Dx® Gastrointestinal Panel 2 (REF 691412, 691413)

Dear QIAstat-Dx customer,

To the Chairman Medical Board and relevant Head-of-Department of the affected healthcare facilities:

This notification is to inform you that QIAGEN® has determined that lots of QIAstat-Dx Gastrointestinal Panel 2, REF 691412 and 691413, are showing a low-frequency increase of false positive results for the *Vibrio cholerae* target. Available data indicates frequency of described event is 0.06% of all runs executed. Although all released lots of these REFs have been confirmed to perform within product specifications, this communication is to inform you about the observed increase and to provide indications regarding how to proceed.

You are receiving this letter because according to our records, you have received at least 1 kit of the affected REFs.

Potential risks associated with the issue

Treatment of suspected gastrointestinal infections is dependent on symptoms and does not rely solely on the real-time RT-PCR result. However, potential risks of a false positive of *Vibrio cholerae* are:

- Potential delay or mask a differential diagnosis for a pathogen not included in the panel or a non-infectious etiology
- Potential administration of unnecessary antibiotic therapy that may result in adverse drug reactions that need to be managed

Action to be taken by the customer/user

If you obtain a positive result for *Vibrio cholerae* in a QIAstat-Dx Gastrointestinal Panel 2 test for which the clinical presentation or epidemiological risk factors are inconsistent with a positive *Vibrio cholerae* result and a false positive result is suspected, please proceed according to these instructions:

- Repeat the test with another cartridge of QIAstat-Dx Gastrointestinal Panel 2, REFs 691412 and 691413.

- If the result is negative in the second run, the first result can be assumed to be a false positive. Please report this to QIAGEN Technical Service through the contact information provided in this letter. Free-of-charge replacements will be provided for the cartridges with such results.
- If the repeat result is positive, the result should be reviewed in accordance with laboratory procedures, clinical presentation, and epidemiological factors. Decisions regarding the status and reporting of results should be in accordance with your laboratory procedures and under the direction of your laboratory director. Consultation with the patient's healthcare provider should be considered.
- Review reportability of the results based on your local requirements.

Action to be taken by commercial partners / distributors

- Forward this Important Notice to your customers.
- Follow-up on the Acknowledgement of Receipt with all of your customers.
- Confirm the completion of the follow up of the Acknowledgement of Receipt of your customers to quality.communications@qiagen.com.
- Complete the Acknowledgement of Receipt as instructed below.

Actions taken by QIAGEN

QIAGEN is actively working to mitigate this detected false positive increase and is implementing actions to further reduce the occurrence of this event.

If you have any questions or concerns, please contact your local QIAGEN Technical Service Department.

QIAGEN Subsidiaries: www.qiagen.com/subsidiaries

QIAGEN Commercial Partners and Importers:
www.qiagen.com/commercialpartnerandistributorsolutions

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

Best regards,
QIAGEN

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Acknowledgment of Receipt Form

Please complete this form and reply via email to **quality.communications@qiagen.com** by March 27, 2026, using the following acknowledgment text (it will be equivalent to your signature):

I hereby acknowledge that I have received, read, and understood the included UFSN “QIAstat-Dx® Gastrointestinal Panel 2 (REF 691412, 691413)”, dated February 27, 2026. 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: