August 31, 2026

Urgent Field Safety Notice

QIAstat-Dx® Gastrointestinal Panel 2 (REF 691413, LOT 250312)

Dear QIAstat-Dx customer,

This Urgent Field Safety Notice is to inform you that QIAGEN® discovered a malfunction in cartridges of LOT 250312 of QIAstat-Dx Gastrointestinal Panel 2, REF 691413. The cartridge serial numbers (453122709, 453122710, 453122712, 453122713, 453122715 and 453122716) within this lot may contain a manufacturing defect that can lead to potential false positive results for one or more analytes reported by the QIAstat-Dx Gastrointestinal Panel 2.

The manufacturing issue has been linked to residual material potentially remaining after the cleaning process. This residue can cause an abnormal reduction of the Cy5 normalization dye signal during qPCR analysis. Under these conditions, the PCR analyzer software may erroneously interpret the baseline fluorescence of the affected targets as a positive amplification signal.

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

Table 1. Affected product and description of the defect

Identifiers	REF 691413
LOT	250312
Expiration date	September 1, 2026
Description of the defect	Unexpected fall of the Cy5 dye leading to false positive signals
Cause of the defect	Manufacturing defect – Residual material remaining

Potential risks associated with the issue

Most cases of gastroenteritis are self-limiting infections and do not require specific nor approved pharmacological intervention. First-line therapy is treatment of symptoms (e.g. vomiting, diarrhea, fluid loss, electrolyte imbalance, etc.) and it is common for any cause of acute diarrhea; rapid rehydration for the replacement of lost fluids and electrolytes. Nevertheless, unnecessary antimicrobial therapy in some false positive cases may result in adverse drug reactions that need to be managed. Most adverse drug events (ADE) are mild to moderate in nature and resolve upon

discontinuation of the offending agent. A false positive result for STEC/*E. coli* O157 could delay appropriate antibiotic administration due to risk for the development of HUS, renal failure, and death. However, based on the type and severity of symptoms, age of the patient (generally young children) and potential reported outbreaks, the false detection may not exclude concern as a possible cause. A false positive result for *Yersinia entercolitica* in a young child with signs and symptoms of appendicitis could delay indicated necessary surgery.

A false positive result might delay or mask a differential diagnosis for a pathogen not included in the QIAstat-Dx Gastrointestinal Panel 2 or a non-infectious aetiology. Treatment of suspected gastrointestinal infections does not rely solely on the real-time RT-PCR result. Therapeutic decisions are also dependent on disease severity, clinical symptoms, patient history, and epidemiological risk factors. For both false positive and false negative results, the lack of correct diagnosis might prevent the benefits of specific treatment if indicated.

A false positive result could lead to the implementation of unnecessary isolation measures or epidemiological investigation. In any case, people with diarrhea of unknown cause would be placed under the standard of care infection control measures until such time the final diagnosis was made; this would not lead to any patient harm.

Detailed description of the issue

A manufacturing defect has been identified in certain devices from LOT 250312. The issue is associated with residues remaining after the cleaning process. Even at trace levels, this residue can cause an abnormal reduction in the Cy5 normalization dye signal during qPCR runs. Consequently, the PCR analysis software may erroneously interpret the altered fluorescence baseline as positive amplification, potentially generating false-positive results for any target detected through the Cy5 channel. The issue has been identified in the following cartridge serial numbers from LOT 250312:

- 453122709
- 453122710
- 453122712
- 453122713
- 453122715
- 453122716

No other serial numbers within the lot has been confirmed as affected.

Action to be taken by the customer/user

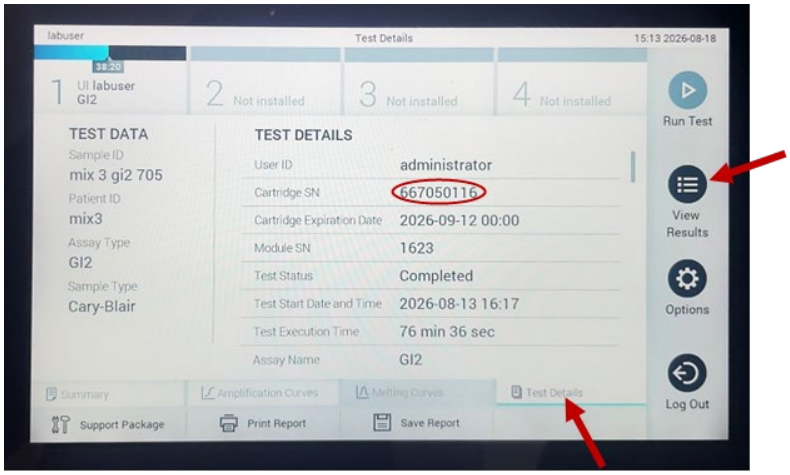
- Review if any of your kits contain any of the affected serial numbers from above or if any was used in an already performed test. To locate and identify the **Serial Number (SN)** in your kits or in your AM follow this guide:

The Serial Number can be found on the aluminum pouch of the cartridge, as shown below:

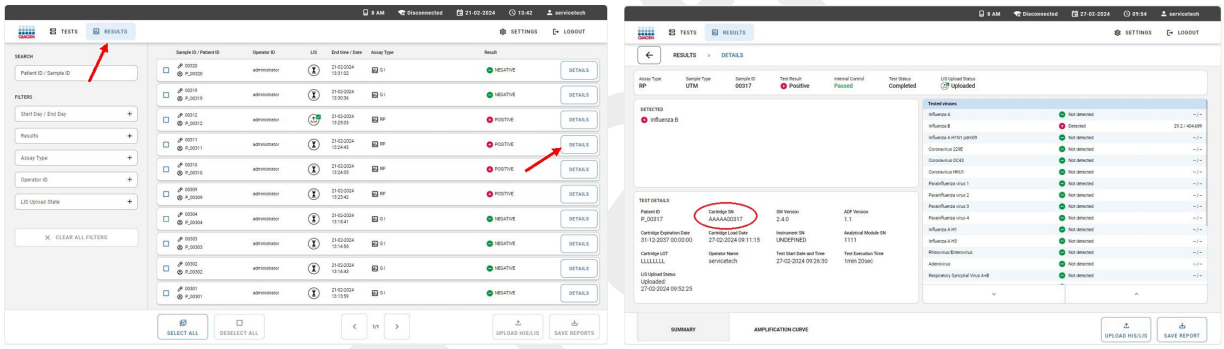
It can also be found on the cartridge label itself as shown in the image below:

Alternatively, the Cartridge Serial Number can be seen directly via software on the instrument screen. Refer to these instructions regarding how to do so for each instrument.

- If your instrument is the QIAstat-Dx Analyzer: From the View Results screen, select the relevant test and press **Test Details**. The Cartridge Serial Number will be displayed as illustrated below:



- If your instrument is the QIAstat-Dx Rise: From the Results screen, select the relevant test and press **Details**. The Cartridge Serial Number is displayed as illustrated below:



- If you have any of the cartridges within the affected serial numbers of LOT 250312, REF 691413, please contact QIAGEN Technical Service for a free-of-charge replacement.
- Dispose the affected cartridge from LOT 250312 in accordance with your national and local safety and environmental regulations.
- If your laboratory has already used cartridges from the affected serial numbers, please reevaluate the analytes reported and the implication of a potential false positive result in light of expected epidemiology and local public health reporting requirements. The malfunction is generally presented as multiple analytes reported. Data of the cartridge run/s can be provided to QIAGEN for evaluation on the potential impact of the malfunction on the reported result.
- Review this notice with your laboratory/medical director.
- **Important**: Forward this information to all individuals and departments within your organization using the above-mentioned serial numbers. If you are not the end user, please forward this notice to the product end user.

- Complete the attached Acknowledgment of Receipt by September 30, 2026.

Actions taken by QIAGEN

All affected material in stock has been blocked. Extensive investigation of this issue is currently ongoing. Containment and mitigation measures have been implemented to ensure that the identified risk is controlled. QIAGEN is actively monitoring the effectiveness of these measures and will implement appropriate corrective and preventive actions based on the outcome of the investigation.

If you have any questions or concerns, please contact your local QIAGEN Technical Service Department through **www.qiagen.com/de-us/knowledge-and-support/product-and-technical-support**

QIAGEN Subsidiaries

https://www.qiagen.com/de-de/contact-us/global-contacts/subsidiaries

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

Sincerely,
QIAGEN

Acknowledgment of Receipt Form

Please complete this form and reply via email to **quality.communications@qiagen.com** by September 30, 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 Urgent Field Safety Notice for QIAstat-Dx Gastrointestinal Panel 2, (REF 691413, LOT 250312), dated August 31, 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 :