Urgent Field Safety Notice

QIAstat-Dx® Respiratory SARS-CoV-2 Panel (cat. no. 691214) LOTs

Acknowledgement of Receipt Form

Please complete this form and reply via email to **quality.communications@qiagen.com** by 02 June 2023, using the following acknowledgement text (which 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 LOTs" dated May 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:

May 2023

Urgent Field Safety Notice

QIAstat-Dx® Respiratory SARS-CoV-2 Panel (REF 691214) LOTs

To the attention of Lab Director/Manager, Medical Director, Risk Manager, Safety Officer

Dear QIAstat-Dx customer,

This Urgent Field Safety Notice is to inform you that QIAGEN has identified a decreased performance reliability rate for specific LOTs of QIAstat-Dx Respiratory SARS-CoV-2 Panel REF 691214, GTIN 14053228038877.

Affected product

Identifiers	REF 691214, GTIN 14053228038877	
LOTs and expiration date	**LOT**	**Expiration Date (YYYY-MM-DD)**
	172043034	2023-06-01
	172043348	2023-08-01
	172043349	2023-06-05
	172043369	2023-08-04
	172044712	2023-08-19
	172046775	2023-09-10
	172048091	2023-09-11
	172048381	2023-09-15
	172048388	2023-09-16
	172048394	2023-09-18
	172048396	2023-09-19
	175010065	2023-09-29
	175010066	2023-09-30
	175010086	2023-10-01
	175010669	2023-10-06

Description of the issue	If cartridges of the affected LOTs are used, an increased frequency of error codes 0xY00094D, 0xY00094E, 0xY00094F, 0xY000950, 0xY000951, 0xY000952, 0xY000953, 0xY0008F0, 0xY014003 or 0xY014008 (where Y is a number between 1 and 4) may occur. These error codes lead to a run abortion.
Cause of the increased frequency of these error codes	Evaporation of the elution reagent from the cartridge over time

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

Potential risks associated with the issue

Run abortions could cause delayed diagnosis since sample testing would have to be repeated. In cases where dry swab sample type is being used, failure would result in new sample to be taken in order to repeat testing.

Actions to be taken by customer/user

- Do not use the remaining stock of cartridges LOTs listed in this Notice. Dispose of it immediately in accordance to your national and local safety and environmental regulations.
- Please contact QIAGEN Technical Services for a free-of-charge replacement.
- Review this notice with your laboratory/medical director.
- 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 the Acknowledgement of Receipt Form attached to this letter by 02. June 2023.
- Actions for Commercial Partners:
    - Forward this Urgent Field Safety 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.

Actions taken by QIAGEN

QIAGEN has implemented immediate measures to ensure that the currently produced cartridges will not have the increased frequency of these error codes.

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

QIAGEN Subsidiaries

www.qiagen.com/de/about-us-old/contact/global-contacts/subsidiaries

QIAGEN Commercial Partners and Importers

www.qiagen.com/de/about-us-old/contact/global-contacts/distributors-and-importers

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

Regards,

QIAGEN