

February 2022

## Urgent Field Safety Notice

NeuMoDx™ Cartridge (REF 100100) LOTs 115424, 115425, 115426, 115427, 115429, 115431

**Attention:** Lab Director/Manager, Medical Director, Risk Manager, Safety Officer

### Affected Product

| Product           | GTIN#          | REF Number | Lot Numbers  |
|-------------------|----------------|------------|--|
| NeuMoDx Cartridge | 10814278020274 | 100100     | 115424, 115425,<br>115426, 115427,<br>115429, 115431 |

### Description of the Issue

QIAGEN has become aware of the potential for false positive results to occur when the above lot of cartridges are used in conjunction with either of the following assays:

- NeuMoDx SARS-CoV-2 Test Strip (REF 300800)
- NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Test Strip (REF 300900)
- NeuMoDx Laboratory Developed Tests (LDTs) for SARS-CoV-2 RNA detection

**Note:** Results for targets other than SARS-CoV-2 are not impacted by this Field Safety Notice.

### Potential Risks Associated with the Issue

False-positive results for SARS-CoV-2 could lead to incorrect management of symptomatic patients, including unnecessary isolation or quarantine, misallocation of resources, delayed diagnosis and treatment for other infections or health conditions, or unnecessary antiviral treatment. False-positive results for SARS-CoV-2 could also lead to cohorting of infected and non-infected patients together, which could result to spread of infection and subsequent increase in morbidity and mortality.

---

## Actions Required by Customers

1. **IMMEDIATELY discontinue** use of the product and discard remaining inventory in accordance with your national and local safety and environmental regulations. Please contact QIAGEN Technical Service for a free-of-charge replacement of scrapped inventory.
2. Share this Field Safety Notice with all users of the NeuMoDx Cartridges in your facility to ensure they are aware of this notice.
3. If you have already used NeuMoDx Cartridges from any of these lots in combination with the NeuMoDx SARS-CoV-2 Assay, the NeuMoDx Flu-A-B/RSV/SARS-CoV-2 Assay and NeuMoDx Laboratory Developed Tests (LDTs) for SARS-CoV-2 RNA detection please review all SARS-CoV-2 positive results to exclude erroneous diagnosis and treatment, except in those cases where alternative confirmation was obtained.

**Note:** results for targets other than SARS-CoV-2 are not impacted by this Urgent Field Safety Notice.

4. Complete the attached response form and return to [Quality.Communications@qiagen.com](mailto:Quality.Communications@qiagen.com) to confirm receipt of this notification.

We sincerely apologize for any inconvenience this may have caused, and thank you in advance for your patience and cooperation. The appropriate Competent Authorities have been made aware.

If you have any questions regarding this notice, please contact **QIAGEN Technical Services**. Your local contact can be found at the following site: (<https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/>).

Sincerely,

Your QIAGEN Team

Trademarks: QIAGEN®, Sample to Insight®, NeuMoDx™ (QIAGEN Group). Registered names, trademarks, etc. used in this document, even when not specifically marked as such, are not to be considered unprotected by law.  
PROM-20346-001 02/2022 © 2022 QIAGEN, all rights reserved.

---

# ACKNOWLEDGMENT FORM

## Urgent Field Safety Notice

NeuMoDx™ Cartridge (REF 100100) Lot 115424, 115425, 115426, 115427, 115429, 115431

Please sign and date below to indicate that you have received and understood this correction notice and have **discontinued use of the product**. Your signature indicates that you have shared the information appropriately within your organization.

**Note:** this document may be shared with regulatory and administrative authorities as required by mandatory legislation. Please print in block letters.

|                                     |  |  |
|-------------------------------------|--|--|
| QIAGEN Account Number (if known):   |  |  |
| Company Name:                       |  |  |
| Your Name and Title (Printed):      |  |  |
| Email address:                      |  |  |
| Telephone Number:                   |  |  |
| Number of Kits Discarded at Site    |  |  |
| Signature (e-signature is accepted) |  |  |
| Date:                               |  |  |

Please email this return response to **Quality.Communications@qiagen.com** or contact your local Technical Service Department to the attention of "QIAGEN Technical Service." Your local contact can be found at the following site: (<https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/>).