NeuMoDx,
a QIAGEN Company

## Urgent Field Safety Notice

## NeuMoDx™ HIV-1 Quant Test Strip

January 2024

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

Dear Valued Customers,

This Urgent Field Safety Notification is to inform you that as a result of internal investigations QIAGEN is issuing an update to the NeuMoDx HIV-1 Quant Test Strip conversion factor.

In summary, NeuMoDx HIV-1 Quant Test Strip results are reported as standard in IU/mL. A conversion factor is then applied to convert the unit of measurement to copies/mL. The Assay Definition File (ADF) and Instructions for Use (IFU) for the NeuMoDx HIV-1 Quant Test Strip currently state a conversion factor of 0.26 (copies/IU), whereas the updated conversion factor is 0.75 (copies/IU). The updated conversion factor results in higher viral loads in copies/mL [0.46 $log_{10}$ copies/mL]. This brings the NeuMoDx HIV-1 Test Strip results in copies/mL closer aligned with other CE-IVD assays and External Quality Assurance (EQA)/Ring trial schemes.

The change in conversion factor does not impact the analytical performance data for the assay documented in the IFU but will result in a change to the corresponding values in copies/mL.

| | IFU data IU/mL | Calculated value in copies/mL using 0.26 as conversion factor | Calculated value in copies/mL using 0.75 as conversion factor |
|---|---|---|---|
| Limit of Detection (LoD) | 34.2 IU/mL (1.5 $log_{10}$ IU/mL) | 8.9 copies/mL (0.9 $log_{10}$ copies/mL) | 25.7 copies/mL (1.4 $log_{10}$ copies/mL) |
| Lower Limit of Quantification (LLoQ) | 34.2 IU/mL (1.5 $log_{10}$ IU/mL) | 8.9 copies/mL (0.9 $log_{10}$ copies/mL) | 25.7 copies/mL (1.4 $log_{10}$ copies/mL) |
| Upper Limit of Quantification (ULoQ) | 7.7 $log_{10}$ IU/mL | 7.1 $log_{10}$ copies/mL | 7.6 $log_{10}$ copies/mL |

## Affected Product

NeuMoDx HIV-1 Quant Test Strip [REF 300500] when used on the NeuMoDx 288 Molecular System and NeuMoDx 96 Molecular Systems.

## Potential Risks Associated with the Issue

The results impacted by this change are those with HIV-1 RNA viral loads of 66.7 to 192.31 IU/mL that previously equated to <50 copies/mL with the existing conversion factor that now equate to results of 50 to 144 copies/mL with the new conversion factor.

HIV management guidelines such as those from European AIDS Clinical Society (EACS) recommend four HIV-1 viral load tests per year. No harm is therefore expected due to these regular viral load monitoring intervals. Transmission of HIV-1 to other individuals a result of the existing conversion factor providing a result of <50 copies/mL carries a negligible risk. Patient guidance, such as from the US Centers for Disease Control and Prevention (CDC), refers to no risk of HIV-1 transmission in individuals with undetectable HIV-1 RNA in plasma , the Terrence Higgins Trust as <20 copies/mL and aidsmap <200 copies/mL respectively.

## Actions Required by Customers

- Review this notice with your laboratory/ medical director.
- **Important**: Forward this information to all individuals and departments within your organization using NeuMoDx HIV-1 Quant Test Strips. If you are not the end user, please forward this notice to the product end user.
- Commercial partners:
  - Forward this notice to your customers.
  - Follow-up on Acknowledgements of Receipt Form with your customers
- Complete "**Acknowledgement of Receipt**" attached to this letter as soon as possible.
- Perform a review of all results obtained since implementation of the assay in your laboratory from individuals with HIV viral loads between 66.7 to 192.31 IU/mL. You should use the new conversion factor to recalculate the results in copies/mL [multiply IU/mL value by 0.75] and review with your HIV physicians as appropriate and identify any results that do not fit the clinical picture in order to determine the need for further evaluation/ retesting.
- The updated Instructions for Use and ADF will be provided as soon as they are available. Should you wish to update results generated by the system in the interim for copies/mL or $log_{10}$ copies/mL. please follow the guidance:

| Result format | Action |
|---|---|
| Current copies/mL to new copies/mL | Multiply system generated copies/mL by 2.8846 |
| Current $log_{10}$ copies/mL to new $log_{10}$ copies/mL | Add 0.460 to system generated $log_{10}$ copies/mL |

## Actions Taken by QIAGEN

- A QIAGEN representative will contact you to schedule the ADF update installation as soon as possible. A service site visit or remote session is required.
- A QIAGEN representative will inform customers when the updated IFU is available.

If you have any questions or concerns, please contact your local QIAGEN Technical Service Department through any of the following: **www.qiagen.com/QIAGEN-Subsidiaries**

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

Sincerely,

Your QIAGEN Team

## Acknowledgment of Receipt Form

Please complete this form and reply via email to quality.communications@qiagen.com *as soon as possible*, 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 NeuMoDx ™ HIV-1 Quant Test Strips (REF 300500) dated January 2024. 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:**