

14th March 2022

Urgent Field Safety Notice

NeuMoDx™ HIV-1 Quant Test Strips (REF 300500)

NeuMoDx™ HCV Quant Test Strips (REF 300300)

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

Affected Product

Product	GTIN#	REF Number
NeuMoDx™ HIV-1 Quant Test Strips	10814278020175	300500
NeuMoDx™ HCV Quant Test Strips	10814278020151	300300

Description of the Issue

QIAGEN has become aware of the potential for over-quantitation of samples with low target concentrations when performing the NeuMoDx™ HIV-1 Quant Assay or the NeuMoDx™ HCV Quant Assay on the NeuMoDx Molecular System. The issue could potentially impact samples run since October 2021.

HIV-1

Samples within the lower half of the quantitative range of the assay may be over-quantitated by up to a factor of 1 log₁₀ IU/ml. QIAGEN has observed this variable quantitation in up to 65% of contrived samples tested internally at medical decision point (200 IU/ml or 2.3 log₁₀ IU/ml). An error flag including a recommendation to repeat the sample was observed in ~50% of over-quantitated HIV-1 samples and acts to alert the user to an error in quantitation.

HCV

Samples with viral loads near the LOD/LLOQ may be over-quantitated by up to a factor of 1 log₁₀ IU/ml. QIAGEN has observed this variable quantitation in up to 95% of contrived samples tested internally at medical decision point (15 IU/ml or 1.2 log₁₀ IU/ml). HCV runs do not generate error flags that would alert the user to an error in quantitation.

Potential Risks Associated with the Issue

HCV

As per current HCV management guidelines, there is no expected risk to HCV patients associated with this low level overquantitation (1).

HIV-1

Over-quantitated HIV-1 results may result in additional sampling, testing and patient anxiety. Treatment decisions and/or medical interventions should not be made on the basis of a singleton result and other diagnostic and clinical information must be taken into account.

Actions Required by Commercial Partners and Distributors

1. **Share this Field Safety Notice** with your customers.
2. **Cease distribution** of the affected product and do not discard inventory. Additional guidance regarding product will be provided in the future.
3. **Follow-up** on the Acknowledgement of Receipt with all your customers.
4. Confirm completion of the follow-up of the Acknowledgement of Receipt of your customers to **quality.communications@qiagen.com**.

Actions Required by Customers

1. **Review results.** QIAGEN recommends that the laboratory director reviews
 - All HIV-1 samples with a result from 34.2 IU/ml to 1E5 IU/ml (1.5 to 5 log₁₀ IU/ml)
 - All HCV samples with a result from 15 to 150 IU/ml (1.2 to 2.2 log₁₀ IU/ml)results generated since October 1, 2021, together with the requesting physician as needed, and identify any results that do not fit the clinical picture in order to determine the need for further evaluation/retesting.
2. **Discontinue testing** with the NeuMoDx™ HIV-1 Quant and HCV Quant Assays. Please do not discard your inventory. Additional guidance will be provided in the future.
3. **Share this Field Safety Notice** with all users of the NeuMoDx™ HIV-1 Quant and HCV Quant Assays in your facility to ensure they are aware of this notice.
4. Complete the attached response form and return it to Quality.Communications@qiagen.com to confirm receipt of this notification.

QIAGEN is working to resolve the issue and will provide additional information on conclusion of our investigation. 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

References: 1. EASL recommendations on treatment of hepatitis C: Final update of the series. Journal of Hepatology 2020vol

