QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
Germany

18th November 2021

Urgent Field Safety Notice

QIAcube® Connect MDx Instrument REF 9003070

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

We would like to inform you that QIAGEN has identified an issue with the text contained within several protocols which run on the QIAcube® Connect MDx instrument. This issue has been observed **only** when using the information screen (secondary screen) which contains inaccurate data for the volume of reagent to be loaded into a tube.

Description of the issue

The issue relates to information given during run set-up, which is intended to guide the user on the volumes of reagents to be added to the tube. During the "Load tip racks and enzymes" step of the run set-up, users have the option to access more detailed information by clicking the **Info** ⓘ button as shown in Figure 1. The screen then switches to a similar screen, as shown in Figure 2, containing the information that a **minimum volume** is to be added instead of the exact volume as detailed in Figure 1.

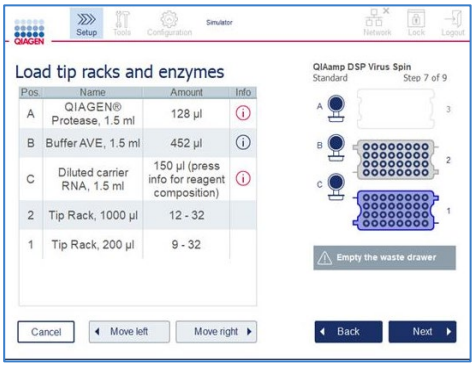

Figure 1 – Run Set-Up Screen.

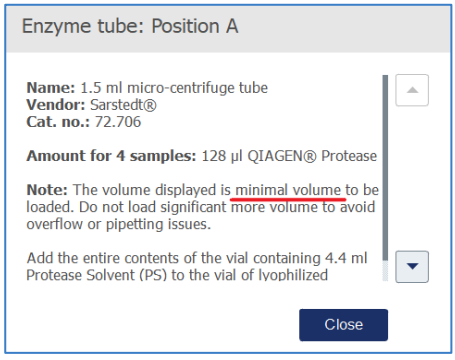

Figure 2 – Screen display after pressing ⓘ.

While the actual amount indicated is accurate, the additional information provided in the Note section does not clearly state that this volume should be exactly loaded onto the instrument.

This issue can affect all serial numbers of the following instrument:

Catalogue number	Product Name
9003070	QIAcube Connect MDx

This issue affects the following protocols:

Protocol Name
DNA_QIAampDSPDNABloodMini_WholeBlood_ElutionVolume100_V1
RNA_PAXgeneBloodRNA(FDA)_Blood_PAXgeneBloodRNAPartAandB_V4
RNA_PAXgeneBloodRNA(CE)_Blood_PAXgeneBloodRNAPartAandB_V4
Virus_QIAampDSPVirusSpin_PlasmaOrSerum_Standard_V2
Virus_QIAampDSPVirusSpin_PlasmaOrSerum_ManualLysis_V2
Virus_QIAampDSPViralRNA_BodyFluid_Standard_V1
Virus_QIAampDSPViralRNA_BodyFluid_ManualLysis_V1
DNA_QIAampDSPDNAMini_BloodOrBodyFluid_Standard_V1
DNA_QIAampDSPDNAMini_BacterialPellet_BacterialDNA_V1
DNA_QIAampDSPDNAMini_Bacteria(Gram-positive)OrYeast_EnzymaticLysis_V1
DNA_QIAampDSPDNABloodMini_WholeBlood_ElutionVolume200_V1

Potential risks associated with the Issue

If a user misunderstands the guidance on the info screen (Figure 2) and pipettes more than the recommended volume detailed on the run set-up screen (Figure 1), it is possible that the tubes will then contain either too much or not enough reagent. This could lead to an over diluted, under diluted, or improperly lysed sample, which in turn would affect downstream processing, leading to a false negative or false positive result, should it not be realized that there has been an issue with sample preparation process.

Additionally, if the user adds too much reagent to the tube, it may cause a spillage that will require a full deep clean of the instrument and could lead to sample loss or delay of results.

Important: Local risk assessments are required to determine the impact of device errors. The use of internal and full process external controls at customer sites may act as an indicator of the device error and help to prevent incorrect results from being reported to the ordering physician, as will internal and external quality assurance testing.

Please note that all instruments are affected by this issue.

Actions to be taken by the Customer/User

1. Follow instructions in the run set-up menu initial screen (Figure 1) and ensure that the volume detailed within the run set-up screen is adhered to using an actual volume only.
2. Upgrade to the latest version of the protocol which is due for release by 01 December 2021 and will be available at **www.qiagen.com** in the QIAcube Connect MDx instrument product page. Apart from correcting the protocol text, no other changes to the protocol will be implemented.
3. Complete the Acknowledgement of Receipt form attached in this letter and return it to QIAGEN ASAP.

Detection of affected batches

Laboratory personnel and clinicians are advised to consider a patient's previous test results, other diagnostic tests, anamnesis, and current clinical condition, if they have followed the information given on the 2nd screen (Figure 2) and added more than the prescribed volume of reagent given in the initial run set-up screen (Figure 1).

If the initial screen was followed and the user added the prescribed volume of reagent, the sample preparation process would be unaffected.

QIAGEN's commitment to resolving the issue

QIAGEN recognizes that this issue may impact your workflow and are currently updating and verifying the affected protocols. New versions of each protocol, as well as instructions on how to install the new versions will be in place by 01 December 2021. The new versions can be downloaded in the QIAcube Connect MDx instrument product page at **www.qiagen.com**.

IMPORTANT NOTE TO IMPORTERS, DISTRIBUTORS, AND COMMERCIAL PARTNERS

QIAGEN have assessed the risk of the issue occurring during routine use of the affected protocol and have determined that this notification should be provided to all customers to ensure that they are informed to follow the information given on the screen in Figure 1 and to ignore the statement of the 'minimal volume' on screen 2. Once the customer is aware of the issue, it would be a suitable mitigation to avoid the risks highlighted within this communication.

Completion of the Acknowledgement of Receipt form

To ensure that all affected users are notified and according to applicable national statutory provisions, we are obliged to provide proof of notification in the market to authorities. Therefore, please complete and sign the included Acknowledgement of Receipt form and email it to QIAGEN Quality Assurance at **Quality.Communications@qiagen.com**.

We regret any inconvenience caused by this situation. If you have further questions, please contact your local QIAGEN Technical Services Department.

QIAGEN Subsidiaries

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

QIAGEN Commercial Partners and Importers

https://www.qiagen.com/about-us/contact/global-contacts/distributors-and-importers/

Best Regards,

Your QIAGEN team

QIAcube Connect MDx User Screen Issue – November 2021

Acknowledgement of Receipt Form

(Please complete this form using block letters.)

I hereby acknowledge that I have received, read, and understood the included Urgent Field Safety Correction described above. We have taken the necessary actions as suggested by this notice:

- The information was forwarded to all individuals and departments within our organization using this product.
- The notice was forwarded to the end user.
- We reviewed this notice with our laboratory/medical director.
- **For commercial partners only**: This notice was forwarded to our customers.
- **For commercial partners only**: We followed-up on the Acknowledgements of Receipt with our customers.

Laboratory/Company name:	
Instrument serial number(s):	
Please confirm the read and understood contents of this notification. ☐ **YES** **DATE: _____** ☐**N/A** (not using any affected protocols detailed) *Please contact QIAGEN Technical Services if you have any additional queries	
Address:	
Contact name:	Title:
Email address:	Phone number:
Signature:	Date: