

January 2022

# Important Note

Dear QIAcube® Connect MDx user,

This note is to share with you an improvement of the protocol support information provided on the graphical user interface of the instrument using the IVD mode of the software.

This improvement is related to information given during run setup, which is intended to guide you on the volumes of components to be provided. During the "Load tip racks and enzymes" step of the run setup, users have the option to access more detailed information by clicking on the Info button.

The pop-up window (as shown in the pictures below) has now been improved to provide unambiguous information about the volume that should be loaded onto the instrument. These changes will only affect the customer supporting information. The protocol steps themselves remain unchanged, so that there is no functional impact.

**Old text:**

Enzyme tube: Position A

**Name:** 1.5 ml micro-centrifuge tube  
**Vendor:** Sarstedt®  
**Cat. no.:** 72.706

**Amount for 4 samples:** 111 µl QIAGEN® Protease

**Note:** The volume displayed is minimal volume to be loaded. Do not load significant more volume to avoid overflow or pipetting issues.

Add 1.2 ml Protease Solvent (PS) to the vial of lyophilized QIAGEN Protease (QP) and mix carefully.

Close

**New text:**

Enzyme tube: Position A

**Name:** 1.5 ml micro-centrifuge tube  
**Vendor:** Sarstedt®  
**Cat. no.:** 72.706

**Amount for 4 samples:** 111 µl QIAGEN® Protease

**Note:** The volume displayed is the exact volume to be loaded.

Add 1.2 ml Protease Solvent (PS) to the vial of lyophilized QIAGEN Protease (QP) and mix carefully.

Close

The following IVD protocols intended for the IVD mode of the software have been updated with the following version numbers:

- DNA\_QIAampDSPDNABloodMini\_WholeBlood\_ElutionVolume100\_V2
- DNA\_QIAampDSPDNABloodMini\_WholeBlood\_ElutionVolume200\_V2
- DNA\_QIAampDSPDNAMini\_Bacteria(Gram-positive)OrYeast\_EnzymaticLysis\_V2
- DNA\_QIAampDSPDNAMini\_BacterialPellet\_BacterialDNA\_V2
- DNA\_QIAampDSPDNAMini\_BloodOrBodyFluid\_Standard\_V2
- Virus\_QIAampDSPViralRNA\_BodyFluid\_ManualLysis\_V2
- Virus\_QIAampDSPViralRNA\_BodyFluid\_Standard\_V2
- Virus\_QIAampDSPVirusSpin\_PlasmaOrSerum\_ManualLysis\_V3
- Virus\_QIAampDSPVirusSpin\_PlasmaOrSerum\_Standard\_V3
- RNA\_PAXgeneBloodRNA(CE)\_Blood\_PAXgeneBloodRNAPartAandB\_V5
- RNA\_PAXgeneBloodRNA(FDA)\_Blood\_PAXgeneBloodRNAPartAandB\_V5

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The new protocol package is available for download on the QIAcube Connect MDx product webpage (<https://www.qiagen.com/QIAcube-Connect-MDx>) under the Product Resources tab. Please refer to the *QIAcube Connect MDx User Manual* (Section 5.11.1, Installing new protocols) for more information on the installation process.

Please note that this package is only intended for updating the protocols mentioned above and does not cover the complete protocol spectrum of the QIAcube Connect MDx. If you need a package of all available protocols, please contact QIAGEN Technical Services.

Due to the nature of the issue, all required regulatory bodies were informed of these details of the protocol issue. As a result of this, QIAGEN requires that all customers complete the attached form and return to QIAGEN Quality Assurance department at [Quality.Communications@qiagen.com](mailto:Quality.Communications@qiagen.com) once they have updated the software. If a customer does not wish to undertake the update, please submit an email to [Quality.Communications@qiagen.com](mailto:Quality.Communications@qiagen.com) detailing the reason.

In case you have any further questions, please reach out to QIAGEN Technical Services or your local QIAGEN representative.

Best regards,

Your QIAcube Connect MDx Team

# QIAcube Connect MDx User Screen Issue – January 2022

## Acknowledgement of Software Update form

(Please complete form using block letters)

I hereby acknowledge that I have received, read, and understood the aforementioned Important Note information and have performed the necessary updates required to incorporate the updated protocols.

- 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):	
<p>Please confirm the instrument(s) detailed above have been updated.</p> <p><input type="checkbox"/> <b>YES</b>    <b>DATE:</b> _____    <input type="checkbox"/> <b>N/A</b> (not using any affected protocols detailed)</p> <p><input type="checkbox"/> <b>NO</b> - Please provide reason:</p> <p>*Please contact QIAGEN Technical Services if you have any additional queries</p>	
Address:	
Contact name:	Title:
Email address:	Phone number:
Signature:	Date: