



QIAGEN GmbH
QIAGEN Str. 1
40724 Hilden, Germany

Acknowledgment of Receipt Form

Please complete this form and email it to quality.communications@qiagen.com within 30 days of receipt of this notice using the following acknowledgement text (it will be equivalent to your signature):

"I hereby acknowledge that I have received, read, and understood the included Urgent Field Safety Notice 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.

We acknowledge that this document may be presented to regulatory or administrative bodies globally according to mandatory legislation."

Laboratory name:

Serial numbers of instruments:

Address:

Contact name:

Title:

Phone number:

Date:

Signature:



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May 2024

Urgent Field Safety Notice

QIAcube® Connect MDx instrument

Cat. no. 9003070, GTIN 04053228039129

To the attention of Lab Director/Manager, Medical Director, Risk Manager, Safety Officer

Dear QIAcube Connect MDx customer,

We are writing to you to inform you that we have identified a potential issue with QIAcube Connect MDx instruments (cat. no. 9003070).

Cat. no.	Product name	GTIN
9003070	QIAcube Connect MDx	04053228039129

Description of the issue

We have encountered an unexpected instrument software issue, which may affect the applications described below:

- QIAamp® DSP DNA Mini Kit (cat. no. 61304), Protocol: Isolation of genomic DNA from Gram-positive bacteria (Script filename: Kt_name_Bacteria (Gram+) or Yeast_Enzymatic Lysis_V2).

The heater shaker module does not perform heating if the temperature is set below 40°C for static incubation steps when running these protocols. Other kits and protocols that can be selected in the IVD mode are not affected by this issue.

If running in the Research mode the following non-IVD applications are affected in the same way : QIAamp DNA Mini Kit (cat. no. 51304, 51306, and 51326) and DNeasy® Blood & Tissue Kit (cat. no. 69504 and 69516) (Script filenames: Kit_name_Bacteria_Gram-positive_Or Yeast_EnzymaticLysis_V1).

Potential risks associated with the issue

We cannot exclude that this may reduce the bacterial pellet lysis efficiency in the protocol "Isolation of genomic DNA from Gram-positive bacteria" with the QIAamp DSP DNA Mini Kit (cat. no. 61304) depending on the lysozyme or lysostaphin that you are using for this step, which could potentially lead to delayed or erroneous results in a downstream assay. (This enzyme and the reaction buffers are not included in the kit.). Temperatures selected at or above 40°C are not affected and do perform as expected.

Actions to be taken by the customer/user

- Complete the Acknowledgment of Receipt promptly and return to quality.communications@qiagen.com
- If running the above protocols and you have selected an incubation temperature for the bacterial lysis below 40°C, then you can ensure precise temperature control by using the heater shaker built into the QIAcube Connect MDx via the **Tools** menu of the software as described below:

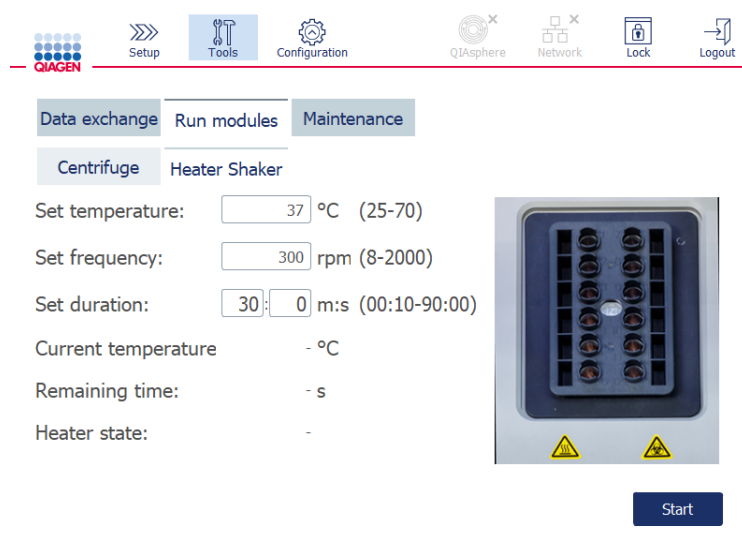


Figure 1. Tool menu to set heater shaker.

To run the protocol without the affected lysis step (after separate pre-lysis), select 0 seconds for the incubation time.

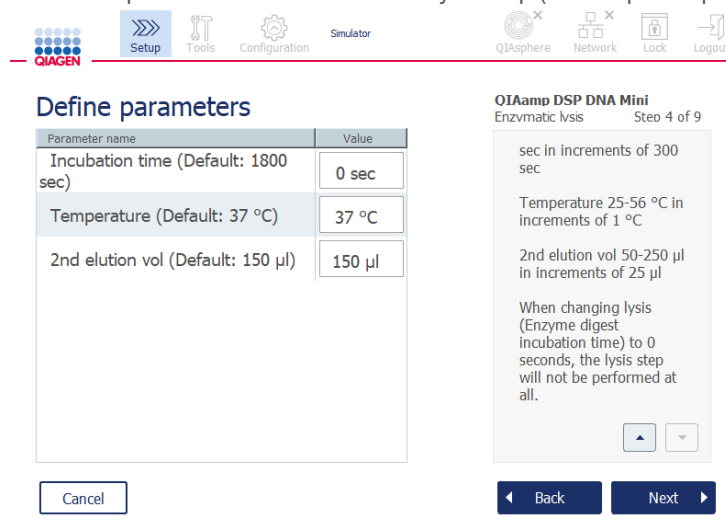


Figure 2. Setting to skip the enzymatic lysis.



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If you wish to check the actual applied temperature in your workflow as currently used, we offer to analyze your logfiles to determine the actual applied temperature. This may help you to confirm these settings. Please contact QIAGEN® Technical Services at (800 362 7737) for assistance.

Actions to be taken by the commercial partner/distributor

- Forward this notice to your customers.
- Follow up on the Acknowledgment of Receipt with all of your customers.
- Confirm the completion of the follow up of the Acknowledgement of Receipt of your customers to quality.communications@qiagen.com.

QIAGEN's commitment for resolution

Our team is currently working on resolving this issue with the next QIAcube Connect MDx software update in a timely manner. We will inform you immediately upon availability of the software update.

If you have any questions or concerns, please contact your local QIAGEN Technical Services through any of the following:

QIAGEN Subsidiaries: www.qiagen.com/de/about-us-old/contact/global-contacts/subsidiaries

QIAGEN Commercial Partners and Importers: www.qiagen.com/de/about-us-old/contact/global-contacts/distributors-and-importers

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

Best regards,
Your QIAGEN Team

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