



## Acknowledgement of Receipt Form

Please complete this form and email it to [quality.communications@qiagen.com](mailto:quality.communications@qiagen.com) by 31 March 2024 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*. 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 Number(s) of Instrument(s):

Address:

Contact name:

Title:

Phone number:

Date:

Signature:

February 2024

## Urgent Field Safety Notice

### EZ2<sup>®</sup> Connect MDx Instrument

REF 9003230 GTIN 045053228040576

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

Dear EZ2 Connect MDx customer,

We are writing to you to inform you that we have identified a potential issue with EZ2 Connect MDx instruments (REF 9003230).

Catalog number	Product name	GTIN
9003230	EZ2 Connect MDx	04053228040576

#### Description of the issue

An issue has been identified with the EZ2 Connect MDx instrument. This is caused by insufficient welding between the heater cable and the heater plate on the heater system. The insufficient welding leads to the heater cable becoming brittle and a consequent disintegration of the cable. Failure of the cable, if not spotted early by a field service technician during a service visit, may cause the instrument to present with following error:

#### ERROR 3481 – HEATER UNABLE TO REACH TEMPERATURE

If the instrument presents with Error 3481 during a run, there is a risk that the run will stop, and the sample being processed will be lost. In this event QIAGEN recommends that the instrument should not be used again until a field service engineer has repaired the unit.

**Note:** This issue can potentially affect all serial numbers of the instrument.

#### Potential risks associated with the issue

If Error 3481 is displayed while the instrument is in use, sample loss could occur which may delay test results. QIAGEN has calculated that the probability of an instrument demonstrating Error 3481 is approximately 0.35%.

If the instrument does not present with Error 3481, it will continue functioning as required.

#### Actions to be taken by the Customer/User

- Complete the *Acknowledgment of Receipt* promptly and return to [quality.communications@qiagen.com](mailto:quality.communications@qiagen.com)

- Should the error described above occurs, please perform the following actions:
  - Switch off the instrument and disconnect from the power supply.
  - Remove any onboard samples and perform decontamination procedure of the instruments as described in the user manual.
  - Call your local QIAGEN Technical Service or the Commercial Partner responsible for QIAGEN products in your country.

### **Actions to be taken by the Commercial Partner/Distributor**

- Forward this notice to your customers.
- Follow up on the *Acknowledgment of Receipt* with all your customers.
- Confirm the completion of the follow up of the *Acknowledgment of Receipt* of your customers to [quality.communications@qiagen.com](mailto:quality.communications@qiagen.com).

### **QIAGEN's Commitment for Resolution**

Regardless of if a fault develops, QIAGEN has initiated a program to replace all heater modules free of charge, by either contacting you directly to arrange a field service engineer visit or at the next on-site visit by a QIAGEN engineer.

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

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

With kind regards,

QIAGEN

[www.qiagen.com](http://www.qiagen.com)