QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
Germany

July 23, 2018

Urgent Field Safety Notice: EZ1 Advanced XL, REF 9001492

Dear EZ1 Advanced XL customer,

We are writing to you to inform you that we have identified a potential issue with a small number of our installed EZ1 Advanced XL instruments (REF 9001492). According to our records you have received at least one of the affected instruments.
The instruments affected by the above potential issue are identified by a **Serial Number where the last 4 digits are between 1801 and 2137**. An example serial number is L095A1801, where “L” denotes the EZ1 Advanced XL instrument, “09” is the year, “5” is the month (note, October, November and December are X, Y and Z respectively), “A” is the production version, and “1081” is the unit identity number.

Detailed description
An issue has been discovered regarding the power branching printed circuit board (PCB) within the EZ1 Advanced XL instrument. Occasionally this has the potential to trigger a malfunction of the instrument heater. Nucleic acid extractions processed during failure of the instrument could be compromised and extractions need to be repeated.

Actions to be taken by the customer/user/commercial partner
In order to assure that your instrument is currently functioning properly, please perform the following temperature function test, which takes no more than 5 minutes once the instrument heater has reached ambient temperature:
1. Put any EZ1 XL Card into the instrument
2. Select “3” in the main menu to select test functions
3. Press ”2” in the test screen to choose the “Temp” operation
4. Set the temperature to “40.0” degrees
5. Press “START”

Observe the “actual” temperature which is displayed. This should rise to 40.0 C +/- 2 degrees within 2 minutes, and a “O” should be displayed next to the temperature value (Figure 1). In this case your instrument is NOT affected by this issue.

Figure 1. EZ1 Advanced XL display following a successful temperature check. Note specifically the “O” after the “actual” temperature

In the event that the “actual” temperature does not rise to 40.0 C, an “X” continues to be displayed next to the temperature value, indicating that ***your instrument is affected by this issue. In this case the nucleic acid eluate from the previous run should be rejected and the sample reprocessed.*** *Contact technical services to arrange a replacement of the faulty component.*

Following failure of the component the instrument may continue to run to completion without a visible alert and the quality of the resulting nucleic acid eluate may be compromised. The next run will not run to completion. In order to assure the quality of your nucleic acid extractions, we would advise that you repeat the brief temperature test and follow the recommendations as described above after every run.

- There is no risk to the operator or environment.
- Forward this information to all individuals and departments within your organization using this instrument.
- If you are not the end user, please forward this notice to the product end user.
- Commercial partners must forward this notice to their customers.
- If the breakdown occurs, **DO NOT** attempt to investigate/repair but contact your local QIAGEN technical services department.

- Review this notice with your laboratory/medical director.
- Complete the Acknowledgement of Receipt form attached to this letter.
- Upon receipt of the Acknowledgement form we will contact you in order to schedule a visit by your local QIAGEN Field Service representative in order to replace the affected part.

QIAGEN's commitment to resolving the issue

QIAGEN will proactively replace the faulty component in all potentially affected instruments. Whilst wishing to inform you of this issue as soon as possible, due to limited part availability, replacement may take up to 6 months to complete.

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 the authorities. Therefore, please complete and sign the included Acknowledgement of Receipt form and either email it to QIAGEN Technical Services at **techservice-eu@qiagen.com** or fax it to **+49 (0)2103-29-22400**.

Actions that have been initiated by QIAGEN

Distribution of the remaining instruments in stock has been put on hold along with the affected spare parts. The root cause of the problem has been identified. Therefore, all other instruments outside of the serial number range stated will not be affected by this issue.

We sincerely apologize for any inconvenience this may cause and thank you in advance for your assistance. If you have any questions, please contact your local QIAGEN Technical Services Department.

Please visit the following webpages for contact information:

- 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/**

With kind regards,

Your QIAGEN Team

07/2018 PROM-12614-002

EZ1 Advanced XL, REF 9001492
Acknowledgement of Receipt form

(Please complete form using block letters)

I hereby acknowledge that I have received, read and understood the included Urgent Field Safety Notice dated July 23, 2018. 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.
- For commercial partners only: This notice was forwarded to our customers.
- We reviewed this notice with our laboratory/medical director.
- For commercial partners only: We ceased the distribution of the affected products. We followed-up on the Acknowledgements of Receipt with our customers.

Laboratory name:	
Instrument serial number:	
Address:	
Contact name:	Title:
Email address:	Phone number:
Signature:	Date: