

28 May 2018

Urgent Field Safety Notice: EZ1 DSP Virus Kit (48); REF 62724, LOTs 160017650, 160017770, and 160020069

Dear EZ1 DSP Virus Kit customer,

We are writing to you to inform you that we have identified an issue with the EZ1 DSP Virus Kit (48), REF 62724, with the following LOT numbers: 160017650, 160017770, and 160020069.

According to our records, you have received at least one kit with these LOT numbers.

A percentage of Reagent Cartridges of these Reagent Cartridge/Kit LOTs does not contain Proteinase K solution in well 10. The use of these kits with LOTs 160017650, 160017770, and 160020069 in analytic workflows could result in incorrect results. A detailed description of the error, additional actions that need to be taken by the customer/user/commercial partner and other important information can be found below.

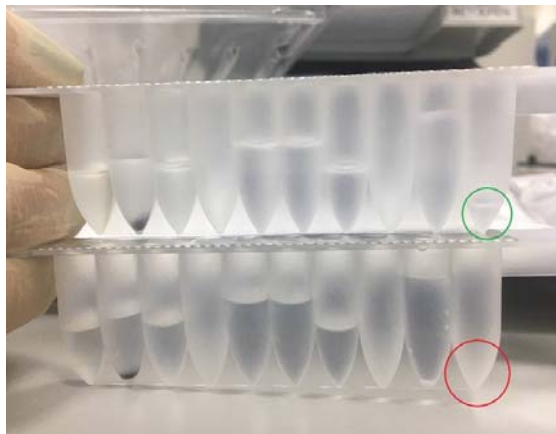
Overview of affected products and lot numbers

Catalog number (REF)	Kit	Kit LOT numbers	Corresponding Reagent Cartridge (REAG CART)	REAG CART LOT number
62724	EZ1 DSP Virus Kit (48)	160017650, 160017770, 160020069	REAG CART VIRUS (RCV)	160011000

Detailed description of issue

We have identified that the kit LOTs 160017650, 160017770, and 160020069 contain a non-conforming EZ1 DSP virus Reagent Cartridge LOT (REG CART VIRUS LOT160011000). In the affected Reagent Cartridges, the Proteinase K Solution in well 10 is missing, i.e. well 10 is empty. See picture 1 below for an example of a correctly filled Reagent Cartridge (marked with a green circle) and a Reagent Cartridge with missing Proteinase K (marked with a red circle). At maximum, eight of the 48 Reagent Cartridges in one kit are affected. All affected Reagent Cartridges are on the Position 6 within the clamshell box (for identification of Position 6 within the clamshell box, see red circle in picture 2).

Picture 1: Example for a Reagent Cartridge with correct filling on well 10 (green circle) and for non-conforming Reagent Cartridge with missing liquid in well 10 (red circle)



Reagent Cartridge with correct filling on well 10

Non-conforming Reagent Cartridge with missing liquid in well 10

Picture 2: Identification of well 10 in position 6 within the clamshell box (see red circle below)



Consequences of the issue

With the affected Reagent Cartridges, the efficiency with which the virus is lysed is potentially reduced. This may lead to under-quantification or false negative results in quantitative downstream assays or to false negative results in qualitative downstream assays. The degree to which lysis efficiency is affected depends on the virus and on the sample type. The internal control (IC) most likely will not detect the reduction in lysis efficiency. Also, full process controls run as independent “samples” might not be suitable to detect the issue as not all Reagent Cartridges are affected.

Actions to be taken by the customer/user/commercial partner

- Forward this information to all individuals and departments within your organization using the above listed kits. 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 you have any remaining stocks of kits with LOTs 160017650, 160017770, 160020069, and/or REAG CART LOT 160011000, **do not** use them. Please contact our technical service for a free-of-charge replacement
- Review this notice with your laboratory/medical director
- If you have used the affected kits with LOTs 160017650, 160017770, 160020069, and/or REAG CART LOT 160011000, we recommend a review of the corresponding results. Consider the possibility of under-quantification and false negative results and evaluate the need for retesting with different EZ1 DSP Virus Kit lots e.g. depending on the clinical presentation and history of the patient
- Dispose of the product in accordance with your national and local safety and environmental regulations
- Complete the Acknowledgement of Receipt form attached to this letter
- Commercial partners:
 - Cease distribution of the products listed in this notice
 - Forward this notice to your customers
 - Follow-up on the Acknowledgement of Receipt with your customers

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 the authorities with proof-of-market notification. Therefore, please complete and sign the included Acknowledgement of Receipt form by 07 June 2018 and email it to: **quality.communications@qiagen.com**.

Actions that have been initiated by QIAGEN

Distribution of the remaining stock of the EZ1 DSP Virus Kit LOTs 160017650, 160017770, 160020069 was halted. As immediate corrective action, the inspection procedure for the Reagent Cartridges has been improved. The root cause of the issue is currently under investigation.

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,

QIAGEN

EZ1 DSP Virus Kit (48); REF 62724 LOTS 160017650, 160017770, 160020069

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 28 May 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 did not use the remaining stocks of the EZ1 DSP Virus Kit (48) LOTS 160017650, 160017770, 160020069, and/or REAG CART LOT 160011000
- We reviewed this Notice with our laboratory/medical director
- If we used an affected the EZ1 DSP Virus Kit (48) LOTS 160017650, 160017770, 160020069, and/or REAG CART LOT 160011000, we reviewed the corresponding results
- We disposed of the affected product in accordance with national and local safety and environmental regulations
- Commercial Partners: we ceased the distribution of the affected products. This information was forwarded to our customers/partners. We followed-up on the Acknowledgements of Receipt with our customers

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