

May 31, 2019

Urgent Field Safety Notice

Filter-Tips, 1500 µl (1024) REF 997024, lots 0605020019, 0605020020, 0635020002, and 0635020003

Dear valued QIASymphony® customer,

We are writing to inform you that we have identified an issue with Filter-Tips, 1500 µl (1024) REF 997024, lots 0605020019, 0605020020, 0635020002, and 0635020003. **These kit lots contain a small percentage of damaged Filter-Tips that are leaking when being used with the QIASymphony SP/AS Instruments (REF 9001297 and 9001301).**

According to our records, you have received at least one filter tip kit of these lot numbers. See Table below.

Affected product and lots

REF	Kit	Kit lots
997024	Filter-Tips, 1500 µl (1024)	0605020019, 0605020020, 0635020002, 0635020003

Detailed description of the issue

A small percentage of the tips are damaged with abrasions inside the tip surface. This abrasion causes tips to leak when being used on the QIASymphony SP/AS Instrument causing liquid dripping into the tip guard and potentially onto the worktable, and/or to loss of transferred liquid volumes.

Potential risks associated with the issue

This issue could lead to loss of samples, lower yield of nucleic acids, less sensitivity in quantification tests, decreased performance of the eluate in subsequent downstream applications, and/or cross-contamination of samples or the resulting nucleic acids. **This could result in delayed or incorrect results when used within a workflow involving subsequent downstream biomolecular nucleic acid analysis.**

Therefore, corresponding effects on results in downstream assays should be considered.

Actions to be taken by the customer/user

- Forward this information to all individuals and departments who are using the above listed kit within your organization. If you are not the end user, please forward this notice to the product end user.
- If you have any remaining stocks of Filter-Tips, 1500 µl (1024) REF 997024, lots 0605020019, 0605020020, 0635020002, and 0635020003, **DO NOT USE** them. For a free-of-charge replacement, please contact QIAGEN Technical Service.
- Dispose of the product in accordance with your national and local safety and environmental regulations.
- Review this notice with your laboratory/medical director.
- If you have used the affected kits with lots 0605020019, 0605020020, 0635020002, and/or 0635020003, we recommend a review of the corresponding results.
- **Complete the Acknowledgement of Receipt form attached to this letter by June 12, 2019 and email it to quality.communications@qiagen.com.**
- 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.

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

If you have any questions or concerns, please contact your local QIAGEN Technical Service Department. For contact information, please visit the following webpages:

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

www.qiagen.com

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Acknowledgement of Receipt Form

(Please complete this form using block letters and email it to quality.communications@qiagen.com by June 12, 2019.)

I hereby acknowledge that I have received, read and understood the included Urgent Field Safety Notice dated 31 May 2019. We have taken the necessary actions as suggested by this notice:

- The information was forwarded to all individuals and departments using this product within our organization. The notice was forwarded to the end user.
- We did not use the remaining stocks of the Filter-Tips, 1500 µl (1024) REF 997024, lots 0605020019, 0605020020, 0635020002, and 0635020003.
- We reviewed this Notice with our laboratory/medical director.
- If we used affected Filter-Tips, 1500 µl (1024) REF 997024, lots 0605020019, 0605020020, 0635020002, and/or 0635020003 we reviewed the corresponding results.
- We disposed of the affected product in accordance with our national and local safety and environmental regulations.
- We acknowledge that this document may be presented to regulatory or administrative bodies globally according to mandatory legislation.

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