



## Acknowledgement of Receipt Form

Please complete this form and reply via email to [quality.communications@qiagen.com](mailto:quality.communications@qiagen.com) on or before 31 December 2024, using the following acknowledgement text (which will be equivalent to your signature):

I hereby acknowledge that I have received, read, and understood the included Urgent Field Safety Notice: QIASymphony® DSP DNA Midi Kit containing defective Reagent Cartridges dated December 2024. We have taken the necessary actions as suggested by this notice.

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:**

**Date:**

**Signature:**

December 2024

## Urgent Field Safety Notice: QIASymphony® DSP DNA Midi Kit Containing Defective Reagent Cartridges

Dear valued customer,

With this notice, we inform you that we have identified an issue with one specific LOT of QIASymphony DSP DNA Midi Kit listed in the table below. Reagent Cartridges of this kit LOT should not be used.

<b>Catalog / REF number</b>	937255
<b>Kit</b>	QIASymphony DSP DNA Midi Kit
<b>LOT</b>	178037679
<b>Affected Material</b>	Reagent Cartridge REAG CART
<b>Reagent Cartridge</b>	178036874

According to our records, you have received at least one kit of the affected kit LOT.

### Description of the issue

A percentage of Reagent Cartridges from the affected kit LOT have incorrect or missing 2D barcodes on the reagent/bead troughs. This can lead to the following consequences when the affected Reagent Cartridges are used with the QIASymphony Instrument:

- (A) An error message is obtained on the QIASymphony instrument due to a failed inventory scan of the affected Reagent Cartridge(s).
- (B) Stop of the instrument during the run.
- (C) The QIASymphony run might be completed, but the eluates from the affected Reagent Cartridges may contain no DNA, a decreased amount of DNA, or low-quality purified DNA.

The investigation of this kit LOT revealed that overall, 6.5% of the Reagent Cartridges were affected of the issue. Nevertheless, there was no pattern found in the affected vs. not affected Serial numbers of Reagent Cartridges, so the percentage of affected cartridges within the kits you have obtained might be significantly higher or significantly lower.

### Potential risks associated with this issue:

- (A) Reagent Cartridge with a failed inventory scan can't be used.
- (B) Stop of the instrument during the run: no eluate will be obtained from the corresponding aliquot of the affected samples.
- (C) No DNA, a decreased amount of DNA, and/or a decreased quality of the purified DNA in the eluates obtained from the runs performed with an affected Reagent Cartridge: This could cause delayed results in a subsequent diagnostic workflow due to

- A delayed availability of the purified DNA for subsequent testing procedure or
- A failure of the DNA a subsequent diagnostic workflow.

If no suitable controls are included as part of a subsequent testing procedure, the downstream application result could be incorrect.

#### **Actions to be taken by the customer/user:**

- Forward this information to all users of the above-mentioned products in your organization. If you are not the end-user, please forward it to the end-user on our behalf.
- Do not use the remaining stock of the affected QIASymphony DSP DNA Midi Kit LOT. Dispose it immediately in accordance with your national and local safety and environmental regulations.
- Review this notice with your laboratory/medical doctor.
- To obtain a free-of-charge replacement, please contact your local QIAGEN® Technical Service.
- If you have already used Reagent Cartridges of the affected LOT, check if the purified DNA is suitable for subsequent use. In case of doubt, repeat the sample with a reagent Cartridge from a different kit LOT.

#### **Actions for Commercial Partners:**

- Forward this Urgent Field Safety Notice to your customers.

#### **Actions taken by QIAGEN:**

QIAGEN is currently taking additional measures to ensure that the kits released after the affected LOT will not have this issue.

If you have any questions or concerns, please contact your local QIAGEN Technical Service Department.

#### **QIAGEN Subsidiaries**

[www.qiagen.com/contact-us/global-contacts/subsidiaries](http://www.qiagen.com/contact-us/global-contacts/subsidiaries)

#### **QIAGEN Commercial Partners and Importers**

[www.qiagen.com/contact/global-contacts/distributors-and-importers](http://www.qiagen.com/contact/global-contacts/distributors-and-importers)

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

Sincerely,

Your QIAGEN Team  
[www.qiagen.com](http://www.qiagen.com)

Trademarks: QIAGEN®, Sample to Insight®, QIASymphony® (QIAGEN Group). Registered names, trademarks, etc. used in this document, even when not specifically marked as such, are not to be considered unprotected by law.

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