Urgent Field Safety Notice

IONA® Nx cfDNA Library Preparation Dx Kit (Part Number: 10141040)

FSCA-identifier: FSN001 18-March-2024 (new)

For Attention of Lab Director/Manager, Medical Director, Risk Manager, Safety Officer

Dear Valued Customers,

This Urgent **Field Safety Notice** is to inform you that we have identified a potential issue with 3 batches of the IONA® Nx cfDNA Library Preparation Dx Kit as detailed in Table 1 below:

Product Affected	Lot Number	Expiry Date
IONA® Nx cfDNA Library Preparation Dx Kit (Part Number 10141040)	10-0047	17-JUL-2024
	10-0048	11-JUN-2024
	10-0049	10-SEP-2024

Table 1: Affected Product

Following an internal investigation it has been identified that adapters YGL005 and YGL006 on the adapter plate (part number 01-09109 lot IN208738) used in the above batches of IONA® Nx cfDNA Library Preparation Dx Kit have been added to the wrong location on the adapter plate. Adapter YGL005 is in the position intended for YGL006 and adapter YGL006 is in the position intended for YGL005.

An in-depth investigation and re-testing of the adapter plates has been conducted to ensure that this issue is limited to two locations only. The investigation has shown that the rest of the adapter plate is **NOT AFFECTED** and can be continued to be used for testing, providing that adapters YGL005 and YGL006 are **NOT USED**.

The IONA® Nx cfDNA Library Preparation Dx Kit is used as part of the IONA® Nx NIPT Workflow to prepare DNA libraries from extracted DNA in preparation for sequencing.

The IONA® test is an *in vitro* nucleic acid screening test that measures the likelihood that a pregnant woman is carrying a fetus with Trisomy 13, 18 or 21, as well as optionally demine fetal sex, screen for fetal sex chromosomes aneuploidy, all other fetal autosomal aneuploidies, and a selection of microdeletions. The IONA® test is intended to be used by a clinician in combination with other risk factors to estimate the risk/chance of an affected pregnancy. The test is not intended to be used as a diagnostic test. Any high-risk results should be followed by confirmatory testing using an invasive sample type.

Potential Risks Associated with the Issue

As two adapters have been put in the incorrect location on the adapter plate, this will result in patient DNA libraries in these two positions being incorrectly identified. The results generated by the analysis software will not be associated with the correct patient ID. Therefore, patient sample results using adapters YGL005 and YGL006 will be transposed and potentially the patient will receive an incorrect

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result for the screening test. This could lead to discordant results, which should be reported to Yourgene Health in the usual way, in line with our Complaint Handling process under our Quality Management system.

Action Required by Customers

- Review this notice with your laboratory/medical director.
- **IMPORTANT**: Forward this notice to all individuals and departments within your organisation using the IONA® Nx cfDNA Library Preparation Dx Kit to ensure they are aware of this **Field Safety Notice.**
- Complete the "**Acknowledgement of Receipt Form**" attached to the last page of this Field Safety Notice within 5 working days.
- **IMPORTANT FOR DISTRIBUTORS and COMMERCIAL PARTNERS**:
    - Forward this notice to your customers who have received the affected product listed in Table 1.
    - Follow-up on the "**Acknowledgement of Receipt Form**" attached to the last page of this Field Safety Notice.
- With immediate effect **do not use** adapters YGL005 and YGL006 for patient samples. The adapter plates can be continued to be used for the remainder of the plate.
- Contact the Yourgene Technical Support Team if you require training on how to exclude patient samples from the adapter plate for adapters YGL005 and YGL006.
- Perform a review of all patient results generated using the affected product as detailed in Table 1. The Yourgene Technical Support Team are available to support this review process, to help identify patient results using adapters YGL005 and YGL006.
- Affected patients with discordant results must be contacted and the results discussed in detail with a Healthcare professional/referring clinician.
- Provide details to Yourgene Health of the amount of stock you have remaining of the affected Library Preparation kits.

Actions Taken by Yourgene Health:

- The Competent (Regulatory) Authority of your country has been notified of this event and has been provided with a copy of this **Field Safety Notice.**
- The EU Authorised Body has been notified and has been provided with a copy of this **Field Safety Notice.**

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- Yourgene Health have reviewed all the QC data for the affected adapter plate and have re-run the sequencing and QC checks on the remainder of the adapters in the plate to ensure that the rest of the plate is unaffected by this issue.

- A thorough root cause investigation is being undertaken to enable us to put additional processes into place to ensure that this issue does not happen in the future.

- Yourgene Technical Support Team will provide training to customers on how to exclude patient samples from the adapter plate using YGL005 and YGL006 adapters.

- The Yourgene Technical Support Team are available to review patient results and advise on the number of potentially affected patients.

We sincerely apologise for any inconvenience this issue may cause and thank you in advance for your patience and cooperation. We will continue to fully support our customers as much as we can to help them navigate this issue.

Contact details of local representative:

Yourgene Health UK,
Skelton House,
Lloyd Street North
Manchester Science Park
Manchester,
M15 6SH,
UK

Tel: +44 (0) 161 669 8122

Email: customerservice@yourgenehealth.com

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Acknowledgment of Receipt Form

Please complete this form and reply via email to **customerservice@yourgenehealth.com** **as soon as possible** (within 5 working days), using the following acknowledgment text (it will be equivalent to your signature):

I hereby acknowledge that I have received, read, and understood the included *Urgent* ***Field Safety Notice*** for **IONA® Nx cfDNA Library Preparation Dx Kit (Part Code: 10141040)** dated 18-March-2024.

We have taken the necessary actions as outlined 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:

Number of Library Preparation kits remaining in stock:

Signature:

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