



29 October 2020

URGENT FIELD SAFETY NOTICE

NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles) FSCA NCR-81110, 29-Oct-2020 - Field Safety Corrective Action

Dear Customer,

In the interest of delivering the highest quality products to our customers, Illumina is contacting you regarding possible leakage of the NextSeq 550Dx reagent cartridge which is part of the NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles).

This notification outlines the issue summary, Illumina actions, and customer actions required.

Table 1: Affected Product:

Product Names	Catalog Number	Lot Number(s)	Expiration Date
NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles) IVD	20028870	A159626-1	08-FEB-2022

Issue Summary

Illumina has identified a manufacturing issue affecting a limited number of NextSeq 550Dx High Output Reagent Cartridges v2* (75 cycles) which are a subcomponent of the NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles). A limited number of the 550Dx High Output Reagent Cartridges v2 (75 cycles) may have been improperly sealed during manufacturing.

Usage of an affected reagent cartridge could lead to underfill during a run resulting in the potential for no or low cluster density.

The NextSeq 550Dx High Output Reagent Cartridge v2 (75 cycles) contains hazardous material which is identified in the Safety Data Sheet (MN 20005425). As stated in the Safety Data Sheet, prolonged or repeated exposure to the material can lead to potential



safety hazards such as causing cancer, fertility damage, danger to the unborn child and/or damage to organs.

In the event of leakage, the user is protected by wearing protective equipment, including eye protection, gloves, and laboratory coat appropriate for risk of exposure, when following the instructions and warnings provided in the NextSeq 550Dx Instrument Reference Guide. The package insert for the NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles) also specifically directs user or operator to the NextSeq 550Dx Instrument Reference Guide.

*Please note the NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles) IVD uses v2 reagent cartridges.

illumina Actions

illumina has identified the root cause of the issue and is implementing corrective a action.

Required Customer Actions

Successfully completed runs with the affected product are not at risk and the results are valid.

Please destroy any inventory of the affected lot per your local procedure and contact Technical Support for a full product replacement. We ask that you complete the attached FSCA NCR-81110 verification form to confirm receipt of this notification and return to Technical Support at techsupport@illumina.com.

We greatly appreciate your continued business and regret any inconvenience this may have caused.

Sincerely,

Gary Workman
Electronically signed by:
Gary Workman
Date: Oct 20, 2020 19:13
PDT

Gary Workman
VP, Global Quality

Karen Gutekunst
Electronically signed by:
Karen Gutekunst
Date: Oct 20, 2020 20:48 PDT

Karen Gutekunst
VP, Regulatory Affairs



29 October 2022

**Field Safety Notice
FSCA NCR-81110 Verification Form**

29 October 2020

Verification Form

Dear Customer,

On October 29th, Illumina sent you an Urgent Field Safety Notice regarding NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycle) lot number A159626-1.

Please complete the table below to confirm that you received the notice, as well as the disposition of the recalled product. Illumina ask that you kindly return the completed form to Illumina within 5 business days using one of the following methods:

- Scan the completed, signed form and email it to TechSupport@illumina.com
- Fax to 858-736-8426, **Attn: Illumina QA**

Product Lots Affected:

Product	Catalog Number	Kit Lot Number	Kit Expiration
NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles) IVD	20028870	A159626-1	08-FEB-2022

Please Complete the Information Below:

Section 1: Customers please complete	
1.1. I have received the Field Safety Corrective Action (FSCA NCR-81110; October 29 th 2020), from Illumina and understand the instructions.	YES:___ NO:___
1.2. I have consumed all kits listed above without incident? If 'Yes' go to question 1.4. If 'No' go to question 1.3.	YES:___ NO:___
1.3. Please list unconsumed Kits Lot Number(s) and Quantity Kit Lot Number: <u>A159626-1</u> Quantity Received: _____ Quantity Used: _____ Quantity to be Replaced: _____	
1.4. Have there been any adverse events associated with the affected product? If 'Yes' add a page to describe the details of the event and email it directly to techsupport@illumina.com	YES:___ NO:___
Customer Informaiton:	

Technical Support: techsupport@illumina.com **Customer Service:** customerservice@illumina.com
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PQN2020-1095 QB11203



Company Name	
Print full name of person completing form	
Print title of person completing form	

Signature of Person Completing Form

Date