



Tuesday, October 28, 2025

Quality Notification
URGENT MEDICAL DEVICE RECALL
URGENT FIELD SAFETY NOTICE

Dear Customer,

Illumina is contacting you regarding a quality issue affecting NextSeq™ 550Dx sequencing reagent kits. Affected products are listed in **Table 1** below. See the Appendix for a list of affected lots.

Table 1: Affected Product (Refer to the Appendix for impacted flow cell lots)

Product Name	Unique Device Identifier – Device Identifier Number	Catalog Number
NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles) IVD	00816270020132	20028870
NextSeq 550Dx High Output Reagent Kit v2.5 (300 cycles) IVD	00816270020118	20028871
CN NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles) IVD	006975709330014	20064341
CN NextSeq 550Dx High Output Reagent Kit v2.5 (300 cycles) IVD	006975709330038	20064344
CN NextSeq 550Dx Mid Output Reagent Kit v2.5 (150 cycles) IVD	006975709330045	20064345
CN NextSeq 550Dx Mid Output Reagent Kit v2.5 (300 cycles) IVD	006975709330052	20064346
FLOWCELL, FIT FLUIDICS TESTING	N/A	15050205

Issue Summary

Flow cells (high output and mid output v2.5) are components of NextSeq 550Dx sequencing reagent kits. Illumina has identified a flow cell gasket quality issue which may lead to flow cell leaks during runs. Please note that, to date, Illumina has not received any reports of adverse events involving patients or operators.

Technical Support:
techsupport@illumina.com

Customer Care:
customercare@illumina.com

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FSN2025 -1783 (Document Number M-AMR-02003)

Page 1 of 7

For any previous runs performed with the affected flow cells, if all runs passed, there is no impact and no follow-up is required. If you experienced a run failure in a previous run using an affected flow cell, please contact Illumina Technical Support.

The quality issue described above can cause liquid to leak under the flow cell gasket and onto the stage of the NextSeq 550Dx instrument. This can cause run failure resulting in:

- No data or insufficient data output.
- Potential instrument fluidics clogs.
- Possible exposure of toxic substances to the user.

Illumina Actions

We have completed a root cause investigation and implemented preventative action to prevent further recurrence. All impacted products in our inventory have been identified and contained.

Illumina has notified the pertinent local and international regulatory bodies, including the Competent Authorities, of this issue.

Required Customer Actions

If you received reagent lots listed in the Appendix, dispose of these reagents per local regulations. See the [NextSeq 550Dx Instrument Reference Guide](#) for additional instructions on proper disposal. Please ensure proper personal protective equipment (PPE) is utilized including, but not limited to, eye protection, gloves, and a laboratory coat. If you have or suspect you have come in contact - directly or indirectly via skin or aerosol - with the reagents in the flow cell, please follow your laboratory's standard safety and first aid procedures immediately.

Please complete the Verification Form to acknowledge that you have carried out the Required Customer Actions above. We kindly ask that you e-mail the completed form to Illumina Technical Support within 5 business days. Alternatively, you may call or e-mail Illumina Technical Support to provide the information requested on the form.

We're Here to Help

If you experience leaking issues, please contact Illumina Technical Support for further evaluation of potential instrument fluidics issues.

If you experience an adverse event due to this issue with the use of the affected products, please report it to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. You can complete and submit the report online at

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www.fda.gov/medwatch/report.htm. In regions outside the USA, please contact your local regulatory authority.

We recognize the impact that a quality issue can have on your operation and are committed to providing you with the highest quality service and support during this process.

For questions or concerns, please contact Illumina Technical Support
techsupport@illumina.com.

Sincerely,



Electronically signed by: VL
Medley
Reason: Approver
Date: Oct 22, 2025 21:34:26 GMT+1

Vicky Medley
Senior Director of Quality



Electronically signed by: Karen
Gutekunst
Reason: Approver
Date: Oct 22, 2025 10:56:57 PDT

Karen Gutekunst
Head of Regulatory Affairs

Why You're Receiving This Notification

You are receiving this notification because our records indicate that you are the appropriate contact for your organization for product changes, product obsolescence, and quality issues.

Please be aware that these notifications contain essential information about our products and are not marketing communications. As such, you may receive these notifications despite having opted-out of receiving marketing communications from Illumina. If you are not the appropriate individual in your organization to receive these notifications, you may unsubscribe from these notifications by [submitting this form](#). For more information, please see our [Privacy Policy](#).

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FSN2025 -1783 (Document Number M-AMR-02003)

Page 3 of 7

Appendix. Affected Flow Cell Lots

Kit Product Description and Catalog Number	Flow Cell Description and Part Number	Flow Cell Lot Number
NextSeq 550Dx HO Rgt Kit v2.5 (75 Cycles) (20028870)	NextSeq 550Dx HO FC Cart v2.5, 75 Cycles (20031098)	A184824-3
		A185016-3
		A183951-3
		A182816-3
		A183339-3
		A182533-3
		A183950-3
		A184531-3
		A182413-3
		A184058-3
		A183613-3
		A183211-3
		A183612-3
		A183826-3
		A182302-3
		A183449-3
		A182298-3
		A182532-3
		A182299-3
		A183830-3
		A183118-3
		A182301-3
		A184359-3
		A184727-3
NextSeq 550Dx HO Rgt Kit v2.5 (300 Cycles) (20028871)	NextSeq 550Dx HO FC Cart v2.5, 300 Cycles (20026365)	A182717-3
		A182051-3
		A179804-3
		A183343-3

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FSN2025 -1783 (Document Number M-AMR-02003)

Page 4 of 7

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Kit Product Description and Catalog Number	Flow Cell Description and Part Number	Flow Cell Lot Number
CN NextSeq 550Dx HO Kit v2.5 (75 Cycles) (20064341)	CN NEXTSEQ 550Dx HO FLOW CELL V2.5 (20062316)	A183402-4
		A183550-4
CN NextSeq 550Dx HO Kit v2.5 (300 Cycles) (20064344)	CN NEXTSEQ 550Dx HO FLOW CELL V2.5 (20062316)	A186185-4
		A183170-4
		A183404-4
		A183555-4
		A183557-4
CN NextSeq 550Dx MO Kit v2.5 (150Cycles) (20064345)	CN NEXTSEQ 550Dx MO FLOW CELL V2.5 (20062530)	A186074-4
		A183278-4
		A183405-4
		A184005-4
CN NextSeq 550Dx MO Kit v2.5 (300 Cycles) (20064346)	CN NEXTSEQ 550Dx MO FLOW CELL V2.5 (20062530)	A185054-4
		A183279-4
		A183409-4
		A183568-4
		A183569-4
		A183570-4
		A184776-4
N/A	FLOWCELL, FIT FLUIDICS TESTING (15050205)	20935999
		20956354

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FSN2025 -1783 (Document Number M-AMR-02003)

Page 5 of 7

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Verification Form

Dear Customer,

Illumina has sent you FSN2025-1783 regarding a quality issue affecting NextSeq 550Dx sequencing reagent kits.

Please complete the Verification Form to acknowledge that you have received this notice. We kindly ask that you email the completed form to Illumina Technical Support. Alternatively, you may call or e-mail Illumina Technical Support to provide the information requested in the form.

Verification Form		
Company Name		
Product/Device Name	Quantity of Impacted Lots Consumed	Quantity of Impacted Lots Discarded
NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) IVD (20028870)		
NextSeq 550Dx High Output Reagent Kit v2.5 (300 Cycles) IVD (20028871)		
CN NextSeq 550Dx High Output Reagent Kit v2.5 (75 Cycles) IVD (20064341)		
CN NextSeq 550Dx High Output Reagent Kit v2.5 (300 Cycles) IVD (20064344)		
CN NextSeq 550Dx Mid Output Reagent Kit v2.5 (150 Cycles) IVD (20064345)		
CN NextSeq 550Dx Mid Output Reagent Kit v2.5 (300 Cycles) IVD (20064346)		
FLOWCELL, FIT FLUIDICS TESTING (15050205)		
Your Information		
Print full name:		
Print title of person completing form:		
Phone Number:		

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FSN2025 -1783 (Document Number M-AMR-02003)

Page 6 of 7

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Customer Responses	
I confirm receipt of FSN2025-1783 and that I read and understood its content.	Yes ☐ No ☐
I confirm that all impacted products on-hand have been destroyed/discarded of.	Yes ☐ No ☐
Distributor/Importer Responses	Not applicable ☐
I have identified customers that received or may have received the product.	Yes ☐ No ☐
I have attached customer list, or I have listed the customers below.	Yes ☐ No ☐
I have received confirmation from all identified customers.	Yes ☐ No ☐
I have informed the identified customers of this recall.	Yes ☐ No ☐ Date (DD-MMM-YYYY):

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Page 7 of 7

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