



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:



Customer Care:



© 2025 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners. For specific trademark information, see



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

Technical Support:

[Redacted]

Customer Care:

[Redacted]

© 2025 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners. For additional information, refer to [Redacted]



[www.fda.gov/medwatch/report.htm](http://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](mailto:techsupport@illumina.com).

Sincerely,

Electronically signed by: [Redacted]  
Reason: Approver  
Date: Oct 22, 2025 21:34:26 GMT+1

Electronically signed by: [Redacted]  
Reason: Approver  
Date: Oct 22, 2025 10:56:57 PDT

### 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](#).

Technical Support:

[Redacted]

Customer Care:

[Redacted]

© 2025 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners. For specific trademark information, visit [www.illumina.com](#)

**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
		A1828163
		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		
A182717-3		
NextSeq 550Dx HO Rgt Kit v2.5 (300 Cycles) (20028871)	NextSeq 550Dx HO FC Cart v2.5, 300 Cycles (20026365)	A182051-3
		A179804-3
		A183343-3

Technical Support:



Customer Care:



© 2025 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners. For additional trademark information, see [www.illumina.com/legal](#).



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
		A1835504
CN NextSeq 550Dx HO Kit v2.5 (300 Cycles)  (20064344)	CN NEXTSEQ 550Dx HO FLOW CELL V2.5  (20062316)	A1861854
		A183170-4
		A183404-4
		A183555-4
CN NextSeq 550Dx MO Kit v2.5 (150Cycles)  (20064345)	CN NEXTSEQ 550Dx MO FLOW CELL V2.5  (20062530)	A183557-4
		A186074-4
		A183278-4
		A183405-4
CN NextSeq 550Dx MO Kit v2.5 (300 Cycles)  (20064346)	CN NEXTSEQ 550Dx MO FLOW CELL V2.5  (20062530)	A184005-4
		A185054-4
		A183279-4
		A183409-4
		A183568-4
		A183569-4
		A183570-4
N/A	FLOWCELL, FIT FLUIDICS TESTING  (15050205)	A184776-4
		20935999
		20956354

**Technical Support:**

© 2025 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners. For more information, visit [www.illumina.com](https://www.illumina.com).

**Customer Care:**



### 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:		

Technical Support:

[Redacted]

Customer Care:

[Redacted]

© 2015 Illumina, Inc. All rights reserved. All trademarks and the property of Illumina, Inc. or their respective owners. The above trademark information is [Redacted]

