Recall

Wednesday, October 27, 2021

Quality Notification

URGENT FIELD SAFETY NOTICE

Illumina is contacting you regarding an issue affecting certain lots of the VeriSeq™ NIPT Sample Prep Kit. Our records indicate that you have received material from these lots. This notification outlines the issue summary, Illumina actions, and customer actions required.

Table 1: Affected Products

Product Name	Part Number	Component Name	Catalog Number	Catalog Lot Numbers
VeriSeq™ NIPT Sample Prep Kit (24 Sample)	20025895	VeriSeq™ NIPT Library Prep Box (24)	20026030	A162813-2 A164108-2 A163501-2
VeriSeq™ NIPT Sample Prep Kit (48 Sample)	15066801	VeriSeq™ NIPT Library Prep Box (48)	15066809	A162738-2 A163577-2

Please see specific impacted index adapter plate barcode numbers in Appendix

Issue Summary

Illumina has received reports of samples in column 11 having low Non-Excluded Sites (NES) resulting in iFACT failures leading to no results. This occurs due to a shift in the library pool indices in column 11 that the sequencing run does not expect causing a sample failure. Illumina has identified 154 out of 704 plates are impacted by this issue. The root cause investigation is still underway.

The Appendix below has the index adapter plate barcodes of the 154 plates affected by this issue.

For any prior runs performed with impacted plates, if all samples have passed, there is no impact and no follow up is required. If you experienced sample failure in a previously completed run with impacted plates, please contact tech support.

The impacted index adapter plates have been kitted in both 24-sample VeriSeq™ NIPT Sample Prep Kit and 48-sample VeriSeq™ NIPT Sample Prep Kits (see lot numbers in the table above).

Technical Support:
techsupport@illumina.com

Customer Care:
customercare@illumina.com

24-Sample Batches

During the 24-sample run, samples get associated with incorrect indices in column 11 due to a sample shift in the index adapter plate. These indices are not expected by the analysis software, causing samples 21 and 22 in wells E3 and F3 of the sample plate to fail. This issue results in iFACT sample failure and leads to a delay in patient results. No incorrect results are generated.

48-Sample Batches

During the 48-sample run, iFACT sample failure will not occur if the kit is used per VeriSeq™NIPT Solution v2 Package Insert instructions because indices in column 11 are not used. The 48-sample kits are included in this notification as an awareness because certain affected adapter plates (listed in Appendix below) were kitted in 48-sample kits (see Table 1 for lot numbers).

Illumina Actions

Illumina has stopped shipment of all impacted kits and is working to implement new quality checks to prevent the occurrence of this issue in the future.

The appropriate Competent Authorities are being notified of this issue.

Required Customer Actions

For 24-sample and 48-sample kits, please use the Appendix below to inspect your current inventory for potentially affected index adapter plates. If you have a plate listed in the Appendix, discontinue use of the impacted plate(s) and destroy per your local procedure. Please contact Technical Support (techsupport@illumina.com) for replacement.

If you have questions about past completed runs, please contact Technical Support or your local FAS.

We ask that you complete the attached FSN2021-1197 Verification Form to confirm receipt of this notification and return to Technical Support at techsupport@illumina.com within 5 business days.

We understand the impact that issues affecting test result delivery can cause. We greatly appreciate your continued business and regret any inconvenience this may have caused.

Technical Support:
techsupport@illumina.com

Customer Care:
customercare@illumina.com

Sincerely,

Electronically signed by: Gary Workman
Reason: Approver
Date: Oct 26, 2021 11:06 EDT

Gary Workman

VP, Quality

Electronically signed by: Karen Gutekunst
Reason: Approver
Date: Oct 26, 2021 09:22 PDT

Karen Gutekunst

VP, Regulatory Affairs

Why You're Receiving This Notification

We are sending this notification to you because our records indicate that you are one of the appropriate contacts for your organization. We occasionally need to inform our customers of product changes, product obsolescence, or quality issues.

Accordingly, please note that these notifications contain important information about our products and are not marketing communications. You may, therefore, receive these notifications even if you have opted out of receiving marketing material from Illumina. If you are not the appropriate individual in your organization to receive these types of notifications, please email customernotifications@illumina.com with the appropriate contact. For more information, please see our Privacy Policy.

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customercare@illumina.com

Appendix:

Affected Plate Barcodes

14514076	14514235	14514249	14514100	14514386	14514344
14514075	14514234	14514248	14514085	14514376	14514343
14514074	14514233	14514247	14514084	14514375	14514342
14514073	14514232	14514246	14514083	14514374	14514341
14514072	14514231	14514245	14514082	14514373	14514340
14514071	14514230	14514244	14514081	14514372	14514339
14514070	14514229	14514243	14514077	14514361	14514338
14514069	14514228	14514242	14514723	14514266	14514336
14514067	14514227	14514241	14514722	14514265	14514335
14514066	14514226	14514240	14514721	14514264	14514399
14514065	14514225	14514239	14514720	14514263	14514390
14514064	14514224	14514238	14514719	14514262	14514389
14514063	14514223	14514237	14514718	14514261	14514388
14514062	14514211	14514236	14514716	14514260	14514334
14514061	14514210	14514360	14514715	14514259	14514044
14514060	14514209	14514359	14514714	14514257	14514043
14514059	14514208	14514358	14514713	14514256	14514042
14514058	14514207	14514357	14514712	14514255	14514040
14514056	14514206	14514356	14514708	14514254	14514039
14514055	14514104	14514355	14514707	14514253	14514038
14514054	14514103	14514354	14514702	14514252	14514037
14514053	14514102	14514353	14514400	14514251	14514036
14514052	14514101	14514352	14514398	14514347	14514035
14514051	14514048	14514351	14514397	14514346	14514349
14514050	14514047	14514350	14514395	14514345	14514348
14514049	14514046	14514045	14514391		

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Recall

FSN2021-1197 **Verification Form**

Dear Customer,

On <DATE>, Illumina sent you an Urgent Field Safety Notice FSN2021-1197 regarding VeriSeq™NIPT Solution v2 Sample Prep Kit Column 11 Index Adapter Plate issue.

Please complete the table below to confirm that you received the notice, as well as the disposition of the recalled product. We 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,** FSN2021-1197 **Notice**
- Return to Illumina at the address and "attn to:" below:
  Attn: Illumina QA, FSN2021-1197 Notice
  5200 Illumina Way, San Diego, CA 92122

Verification Form				
Company Name				
Product/Device Name	**Catalog Number**	**Part Number**	**Lot Number**	**Quantity Shipped**
Your Information				
Print full name:				
Print title of person completing form:				
Customer Responses				
I confirm receipt of FSN2021-1197 customer communication and that I read and understood its content.	Yes ☐ No ☐			
I have performed all relevant actions requested by this communication.	Yes ☐ No ☐			
The information and required actions have been brought to the attention of all relevant users and actions have been executed.	Yes ☐ No ☐			
Product has been consumed. No affected kits are available for return, destruction, or inspection.	☐			

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I have completed the inspection and kits are appropriate for use.	☐
I have destroyed affected devices	☐
Other actions (if any):	
Quantity Consumed:	Date Complete (DD/MM/YY)
Lot/Serial #(s) and Quantity:	
Comments:	

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	Date (MM/DD/YY)

Signature of Person Completing Form

Date

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