



Sunday, July 4, 2021

Quality Notification
URGENT FIELD SAFETY NOTICE

Dear Customer,

In the interest of delivering the highest quality product and support to our customers, Illumina is contacting you regarding an issue potentially affecting customers that purchased certain lots of the VeriSeq™ NIPT Sample Prep Kit, previously communicated via [PQN2021-1169](#). Our records indicate that you have received material from these lots. This follow-up communication provides further details on the issue summary, Illumina actions, and customer actions required.

Table 1: Affected Products

Product Names	Catalog Number	Catalog Lot Numbers	Component Name	Part Number
VeriSeq NIPT Sample Prep Kit (24 Sample)	20025895	A162301, A162261	Library Prep Kit Box (24 Sample)	20026030
VeriSeq NIPT Sample Prep Kit (48 Sample)	15066801	A161869, A162106	Library Prep Kit Box (48 Sample)	15066809
VeriSeq NIPT Sample Prep Kit (96 Sample)	15066802	A162522, A162609	Library Prep Kit Box (96 Sample)	15066810

Issue Summary

The VeriSeq™ NIPT Solution v2 is an in vitro diagnostic test intended for use as a screening test for the detection of genome-wide fetal anomalies from maternal peripheral whole blood specimens in pregnant women of at least 10 weeks gestation.

Illumina has received reports of non-reproducible, discordant, or discrepant results associated with the lots listed in Table 1. Preliminary investigation has identified that the 6 lots in Table 1 are impacted and they share the same lot of index adapter plate.

These plates have unique serial numbers in order of their manufacturing and initial analysis has allowed us to determine that fewer than 5% of the plates are impacted. Preliminary investigation has revealed an error in the index placements in column 1 for a subset of this lot of index plates. If an affected plate is used, it can lead to index mis-association for samples in column 1, which could lead to incorrect results.

Technical Support:
techsupport@illumina.com

Customer Service:
customerservice@illumina.com

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illumina Actions

illumina has stopped shipment of all impacted kit lots and is investigating further. illumina will provide replacement VeriSeq™ NIPT Sample Prep Kits.

The appropriate Competent Authorities are being notified of this issue.

Required Customer Actions

illumina requests customers to discontinue use of the affected lots immediately, as use of these lots could lead to incorrect results. Contact your local Field Application Scientist (FAS) to return the kit boxes listed in Table 1. In the event you are unable to return it, please destroy any affected lots per your local procedure and contact your FAS for a full replacement.

If you have previously processed samples from the affected lots indicated in Table 1, illumina recommends that these samples from column 1 be re-tested, unless you make the independent determination it is not medically necessary.

We ask that you complete the attached FSN2021-1171 Verification Form, beginning on Page 3, 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 potentially affecting test results can cause. We greatly appreciate your continued business and regret any inconvenience this may have caused.

Sincerely,



Gary Workman

Vice President of Global Quality

*Electronically
signed by: Gary
Workman
Reason:
Approver
Date: Jul 2,
2021 22:44 PDT*



Karen Gutekunst

Vice President of Regulatory Affairs

*Electronically
signed by: Karen
Gutekunst
Reason:
Approver
Date: Jul 2, 2021
16:41 PDT*

Technical Support:

techsupport@illumina.com

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FSN2021-1171 Verification Form

Dear Customer,

Please complete the table below to confirm that you received the notice. Illumina asks that you kindly scan the completed, signed form and email it to techsupport@illumina.com within 5 business days.

FSN2021-1171		
Component Name	Part Number	Quantity Returned
Library Prep Kit Box (24 Sample)	20026030	
Library Prep Kit Box (48 Sample)	15066809	
Library Prep Kit Box (96 Sample)	15066810	
Customer Responses		
I confirm receipt of the FSN2021-1171 customer communication and that I read and understood its content.		Yes <input type="checkbox"/> No <input type="checkbox"/>
The information and required actions have been brought to the attention of all relevant users and actions have been executed.		Yes <input type="checkbox"/> No <input type="checkbox"/>
I have performed all relevant actions requested by this communication. Select one of the following:		Check One: <input type="checkbox"/> All product has been consumed. No affected product is available for return. <input type="checkbox"/> I have leftover affected product to send back to Illumina. <input type="checkbox"/> I have discarded all affected product. No affected product is available for return.
If discarding the product, please provide the barcodes of the index adapter plates present in the library prep kits:		
Quantity of Potentially Affected Product Consumed:		
Lot/Serial #(s) and Quantity:		
Comments:		

Technical Support:
techsupport@illumina.com

Customer Service:
customerservice@illumina.com

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Distributor/Importer Responses	Not Applicable <input type="checkbox"/>
I have identified customers that received or may have received the product.	Yes <input type="checkbox"/> No <input type="checkbox"/>
I have attached customer list, or I have listed the customers below.	Yes <input type="checkbox"/> No <input type="checkbox"/>
I have received confirmation from all identified customers	Yes <input type="checkbox"/> No <input type="checkbox"/>
I have informed the identified customers of this Field Safety Notice FSN2021-1171 VeriSeq NIPT Solution v2 Results.	Date (MM/DD/YY)

Company Name: _____

Print Full Name: _____

Print title of Person Completing Form: _____

Signature of Person Completing Form: _____

Date: _____

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