



Tuesday, June 29, 2021

Customer Notification – VeriSeq™ NIPT Solution v2 Non-Reproducible, Discrepant, and Discordant Results

Dear Customer,

Illumina is contacting you regarding an issue potentially affecting customers that purchased certain lots of VeriSeq™ NIPT Sample Prep Kit. Please see below for Products Affected, Potential Effect, and Investigation and Next Steps.

Products Affected

Catalog Number	Products Affected	Lot Numbers
20025895	VeriSeq NIPT Sample Prep Kit (24 Sample)	A162301, A162261
15066801	VeriSeq NIPT Sample Prep Kit (48 Sample)	A161869, A162106
15066802	VeriSeq NIPT Sample Prep Kit (96 Sample)	A162522, A162609

Potential Effect

Illumina has received elevated customer complaints around non-reproducible, discrepant, and discordant results associated with the lots listed in the table above.

Investigation and Next Steps

Please discontinue use of these kits immediately. A follow up communication will be forthcoming. Please do not use or discard the lots listed in the table until you receive additional information from Illumina.

Illumina is currently investigating the issue and has contained remaining inventory of these lots.

Technical Support:
techsupport@illumina.com

Customer Service:
customerservice@illumina.com

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We're Here to Help

Illumina understands 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, if you have encountered the issue explained above, or if you reported any patient test results using the potentially affected plates prior to receiving this notice, please contact Illumina Technical Support at techsupport@illumina.com. Illumina greatly appreciates your continued business.

Sincerely,

Gary Workman

Electronically signed
by: Gary Workman
Reason: Approver
Date: Jun 29, 2021
15:08 PDT

Karen Gutekunst

Electronically signed
by: Karen Gutekunst
Reason: Approver
Date: Jun 29, 2021
14:44 PDT

Gary Workman
Vice President of Global Quality

Karen Gutekunst
Vice President of 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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