Agilent Technologies

Agilent Technologies, Inc.
5301 Stevens Creek Blvd.
Santa Clara, CA, 95051, USA
www.agilent.com

Attention: Laboratory Manager
Reference number: PI000000345

March 17, 2025

URGENT FIELD SAFETY NOTIFICATION

Subject: GenetiSure Dx Female Reference DNA Low Level Mosaic Aberration, K1201-64105 and 5190-7317

Dear Valued Customer,

The purpose of this letter is to notify you that we have identified a low level mosaic aberration in chromosome 12 in the Human Reference DNA Female aliquot (5190-7317) contained within the -20C product, K1201-64105 GenetiSure Dx Labeling Kit.

Our records indicate that you may have received the affected lot of GenetiSure Dx Labeling Kit containing the Human Reference DNA Female aliquot. If you have a product from an affected lot, please do not use the product and contact Agilent, as indicated below, to obtain a replacement.

Description of the issue

A low level mosaic aberration in chromosome 12 has been observed in the female reference DNA. Although the product met all quality control specifications when manufactured, a full chromosome low level log ratio has been observed in chromosome 12 (LR: -0.09). This will be seen only when the affected Agilent Female DNA lot is being used as a reference. This issue is limited only to chromosome 12, and the data generated can be analyzed using the CytoDx functionalities by displaying the moving average line in the Genome View, Chromosome View, or Gene View of the Triage View.

TABLE 1. Affected Product and Lot Numbers

	Product Name	Part Number	Affected Lot Numbers
1	GenetiSure Dx Labeling Kit Human Reference DNA Female aliquot (Part Number 5190-7317, Lot Number 0006793917)* *Only available as part of the GenetiSure Dx Labeling Kit	K1201-64105	0006798023

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Evaluation of risk

The affected lot of GenetiSure Dx Postnatal assay was released to customers with a component (Human Reference DNA Female aliquot) observed to have a low level mosaic aberration that may result in a baseline shift on female DNA sample on Chromosome 12. This in turn may generate false positive or false negative results.

As described in the instructions for use (IFU), the GenetiSure Dx Postnatal assay results are intended to be used in conjunction with other clinical and diagnostic findings, including confirmation by alternative methods and clinical genetic evaluation. False positive results will likely be detected by such confirmatory methods. False negative results may raise the clinical concern of missing a clinically relevant chromosomal CNV or cnLOH. False positive or negative results may result in a delay in diagnosis. In rare instances where there is a treatable genetic disorder, a delay may result in harm or death to the patient. However, performance of confirmatory testing in accordance with the IFU is expected to mitigate this risk.

Actions to be taken by the customer

1. Please check your inventory and identify if you have the affected product/lot listed in Table 1.
2. Confirm the number of affected kits in your possession and discard any unused kits.
3. Please indicate the number of requested replacement kits on the enclosed Acknowledgement Form.
4. Please confirm that you have received, read, and understood this Field Safety Notification by completing and signing the enclosed Acknowledgement Form and returning it to fieldactions.notifications@agilent.com.

Transmission of this notice

We kindly ask you to inform those who need to be aware of this notification within your organization or any other organization to which the affected product(s) have been transferred. Please ensure that your organization maintains awareness of this notice.

Thank you for your attention to this matter. We apologize for any inconvenience this action may cause, and we appreciate your understanding as we ensure customer satisfaction.

Sincerely,

Brenda Tregellas
VP, Global Quality, Life Sciences and Diagnostics Group (LDG)
Agilent Technologies, Inc.

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Account name:
Account number:
Country:

Acknowledgement Form for Customers
Agilent Reference Number: PI000000345

Fill out this Acknowledgement Form to confirm receipt of the enclosed Field Safety Notification regarding **GenetiSure Dx Labeling Kit, K1201-64105 and Human Reference DNA Female aliquot, 5190-7317**.

Please complete the Acknowledgement Form within 7 days from receipt and email the form to fieldactions.notifications@agilent.com. Technical support will follow up and replace the impacted kits.

Acknowledgement:				
1. I have read and understood the Field Safety Notice and the instructions stated in this letter:			Yes ☐ No ☐	
2. Do you have any affected items in your in stock? Please check your inventory before answering this question. If the answer to this question (question 2) is "yes", please fill in the number of items discarded as well as the quantity of replacement items required in the table below.			Yes ☐ No ☐	
Product code	Product name	Lot(s)	Number of items discarded	Number of items to be replaced
K1201-64105	GenetiSure Dx Labeling Kit Human Reference DNA Female aliquot (Part Number 5190-7317, Lot Number 0006793917)* *Only available as part of the GenetiSure Dx Labeling Kit	0006798023		
Date				
Company name				
Company address				
Company country				
Name of person completing this form				
e-mail address				
Phone number		+		
Signature				