FSN Ref: 2023-05

Date: 2023-10-13

Urgent Field Safety Notice
AlloSeq Assign

For Attention of: Users of product AlloSeq Assign

Contact details (name, e-mail, telephone, address etc.)
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1. Information on Affected Devices*	
1.	1. Device Type(s)
	AlloSeq Assign
1.	2. Commercial name(s)
	AlloSeq Assign
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)
	The intended use of the AlloSeq Assign software manufactured by CareDx Pty Ltd is to assist the user to assign a genotype following targeted enrichment and sequencing using the AlloSeq Tx reagent kits. AlloSeq Assign software imports sequence data, performs sequence alignment, enables sequence editing and then compares a consensus sequence with a library of sequences of alleles. The product is intended for use in appropriately regulated laboratories. The software is for professional use only and must not be used as the sole basis for clinical decisions. The AlloSeq Tx kits and Software are not used for the diagnosis of disease.
1.	5. Device Model/Catalogue/part number(s)
	ASA1.0
1.	6. Software version
	1.0.3, 1.0.4, 1.0.5
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	N/A

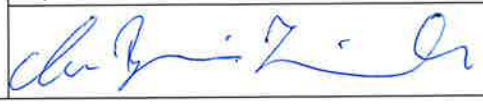
2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	The Ctrl+G shortcut and the P only or G only selections in the Report Display Options are removing the expression variant indicator (N) from the end of null allele when displaying the results in G-groups and P-groups. This impacts the Summary screen in the UI and the Summary Table report. No other report formats are impacted.
2.	2. Hazard giving rise to the FSCA
	There is a discrepancy in the results displayed on the Coverage pane and Summary screen in the UI and in the Summary table report. Expression variant indicators are removed, reporting an allele that does not exist in any known database.
2.	3. Probability of problem arising
	The problem is isolated to the Ctrl+G shortcut and selection of P Only or G Only in the Report Display Options. When manually displaying the G-group or P-group the expression variant indicator (N) is not removed and the summary report also displays the expression variant indicator (N).
2.	4. Predicted risk to patient/users

	When using the Ctrl+G shortcut or the P only or G only in the Report Display Options, the expression variant indicator (N) is removed when displaying the G-group or P-group. This can cause alleles to appear to be expressed when they are not.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The Ctrl+G functionality was demonstrated during a training session held on 28th September, 2023. The Ctrl+G shortcut function can be used to display allele groups in their respective G-group or P-group. When the Ctrl+G shortcut is used and an expression variant is present, the expression variant indicator (N) is absent from the G- or P-group display and from the Summary Table report format. No other report formats are impacted. Further investigation showed that the P only and G only selection in the Report Display Options is also impacted. This issue is present in AlloSeq Assign v1.0.3 forward. There is potential for incorrect reporting of expression variant alleles as the indicator is removed from the G- or P-group display and Summary Table report. Expression variants are not commonly present; therefore, the likelihood of misreporting is low. Additionally, removal of the N indicator results in allele name that does not exist in any known database, which should be, with high likelihood, detected by a trained professional and integrated reporting systems. Only the Summary Table report in impacted and all other report formats commonly used report the allele correctly.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Describe: • Download the updated IFU from CareDx website (www.caredx.com) • Return Customer/Distributor Reply Form	
3.	2. By when should the action be completed?	01 Nov 2023
3.	3. Particular considerations for: IVD No	
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes

3.	**5. Action Being Taken by the Manufacturer**
	☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None • CareDx will update the IFU to remove reference to the Ctrl+G shortcut and the P only and G only options in the Report Display Options.

	• CareDx will release a new version of AlloSeq Assign in March 2024.	
3	6. By when should the action be completed?	New IFU will be available 13Oct2023. Software update will be released in March 2024.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	N/A	

	4. General Information	
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. Further advice or information already expected in follow-up FSN?	No
4.	4. Manufacturer information (For contact details refer to page 1 of this FSN)	
	a. Company Name	CareDx Pty Ltd
	b. Address	20 Collie Street, Fremantle, WA 6160, Australia
	c. Website address	www.caredx.com
4.	5. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	6. List of attachments/appendices:	Distributor or Customer Reply Form
4.	7. Name/Signature	Anna Bereza-Jarocinska Regulatory Affairs (Post Market Surveillance) Specialist
		

	Transmission of this Field Safety Notice
	This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.