FSN Ref: 2024-01

Date: 26-Jul-2024

Urgent Field Safety Notice
AlloSeq HCT Software

For Attention of: Users of product AlloSeq HCT Software

Contact details (name, e-mail, telephone, address etc.)
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1. Information on Affected Devices*	
1.	1. Device Type(s)
	AlloSeq HCT Software
1.	2. Commercial name(s)
	AlloSeq HCT Software
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)
	The AlloSeq HCT Software is intended to be used with the AlloSeq HCT reagent kit to calculate the percent genomic DNA (gDNA) from each individual's genome present within the transplant recipient's blood. 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 HCT kits and Software are not used for the diagnosis of disease.
1.	5. Device Model/Catalogue/part number(s)
	ASHCTS2
1.	6. Software version
	V2.2.0, V2.2.1
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
	An unusual result from post-transplant samples with AlloSeq HCT Software v2.2.1 has been reported. There is a post sample, reported R: 0.4%, D: 49.6%. The patient pre/donor GT has been used for previous chimerism analysis, and there were no problems. As per IFU108_AlloSeq HCT Software v2 IFU CE, "The AlloSeq HCT kit is intended to be used to measure the % donor(s) and % recipient DNA present in a single sample in allogeneic HSCT recipients." It clearly refers to fractions, which are commonly understood to be a subset of the whole (100%). The sum of % result should add up to 100% or very close, due to there being some noise in the sequencing. The customer recognized this result as unusual and immediately reported to CareDx.
2.	2. Hazard giving rise to the FSCA
	The result in the Batch screen cannot be used for reporting, correct results need to be obtained from the Analysis Details page.
2.	3. Probability of problem arising
	This is a very rare occurrence, where a single informative homozygous marker is present. A typical unrelated transplant has 25 or more informative homozygous markers.
2.	4. Predicted risk to patient/users

	Low. The occurrence is very rare, and the incorrect result is obvious, and the results can be obtained from the analysis detail page rather than the batch screen.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The root cause has been identified as a rare circumstance where there was only one remaining homozygous marker present in the analysis, and the homozygous result is set to zero (essentially 'not present'). When averaged with a high heterozygous result this can produce a case where the final total is effectively half of what it should be.
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 IFU108_AlloSeq HCT Software v2 IFU CE from CareDx website • Download the updated TEC935_AlloSeq HCT Software – Known Anomalies from CareDx website	
3.	2. By when should the action be completed?	16Aug2024
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 • Update IFU108_AlloSeq HCT Software v2 IFU CE to v8.0 • Update TEC935_AlloSeq HCT Software – Known Anomalies to v2.0	
3	6. By when should the action be completed?	26Jul2024
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 [redacted]

	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.