FSN Ref: 2022-04

Date: 2022-09-01

Urgent Field Safety Notice
QTYPE

For Attention of: Users of product QTYPE lots E049, E050, E051, E052, E053, E054, E055, E056, E057, E058, E059 and E060

Contact details (name, e-mail, telephone, address etc.)
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1. Information on Affected Devices*	
1.	1. Device Type(s)
	Olerup QTYPE 11 kits consist of qPCR plates containing pre-aliquoted and dried reaction mixes in each well, together with Master Mix provided in separate vials
1.	2. Commercial name(s)
	Olerup QTYPE 11
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)
	Olerup QTYPE 11 HLA Typing Kits are qualitative in vitro diagnostic tests for the DNA typing of HLA Class I and Class II alleles. The kits are to be used as an aid in determining HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and/orDPB1 alleles with low to intermediate resolution in human genomic DNA samples extracted from anticoagulated blood, to aid in transfusion and transplantation donor and recipient matching. Olerup QTYPE 11 kits are for professional use only and must not be used as the sole basis for making clinical decisions.
1.	5. Device Model/Catalogue/part number(s)
	201.701-03/10
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	E049, E050, E051, E052, E053, E054, E055, E056, E057, E058, E059 and E060
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	A known B*50:01:01:02 sample was typed as B*50:02 due to an incorrect reactivity in the mix in H7 FAM. B*50:01:01:02, B*50:01:01:08, B*50:01:08, B*50:01:18, B*50:51, and B*50:57 were not included in the string of potential result options due to the error, which has now been corrected. This applies to all active QTYPE lots (E049-E060).
2.	2. Hazard giving rise to the FSCA
	A known B*50:01:01:02 sample was typed as B*50:02 due to an incorrect reactivity in the mix in H7 FAM. The serological split within the B*50 group caused a serological mistyping.
2.	3. Probability of problem arising
	The problem is only seen in samples with the rare alleles B*50:01:01:02, B*50:01:01:08, B*50:01:08, B*50:01:18, B*50:51, or B*50:57.

2.	4. Predicted risk to patient/users
	Low
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	HLA-B result is reported as B*50:02 instead of B*50:01:01:02 due to incorrect reactivity in well H7 FAM. The serological split within the B*50 group caused a serological mistyping.
2.	7. Other information relevant to FSCA
	This issue will affect all lots from E049 when analysed with a kit file older than Typingkit_QTYPE_20220825.

	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: • Update to typingkit_QTYPE_20220825.vda file. • Return signed Customer/Distributor Reply Form	
3.	2. By when should the action be completed?	Typing kit file to be updated as soon as possible. Completed Customer Reply to be returned by 2022-Sep-16
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 The Olerup QTYPE 11 kit file has been updated and reaction H7 FAM has received a specificity change in typing kit file Typingkit_QTYPE_20220825.vda	
3	6. By when should the action be completed?	2022-Aug-26
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 AB
	b. Address	Franzéngatan 5, 112 51 Stockholm, Sweden
	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 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.