FSN Ref: 2022-05

Date: 2022-09-23

Urgent Field Safety Notice
QTYPE

For Attention of: Users of product QTYPE lots E050, E051, E053, E054, E055, E056, E057, E058, E059, E060 and E061

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
	E050, E051, E053, E054, E055, E056, E057, E058, E059, E060 and E061
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	The mix located in position O21 in the O560 channel on the QTYPE plate is designed to amplify the DPB1*10:01 allele, but has been reported to be false negative in two DPB1*10:01,17:01 samples due to a lower relative final fluorescence (rFF) than the threshold. The resulting interpretation is that of DPB1*09:01,17:01 instead of DPB1*10:01,17:01. The root cause has been identified as competitive amplification between the DPB1*10:01 and DPB1*17:01 alleles, whereby the alleles are both amplified by the primers in the mix, but DPB1*17:01 is excluded by the probe. The sequence homology between the DPB1*10:01 and DPB1*17:01 alleles result in a lower amplification curve than that which is expected from a DPB1*10:01 homozygous sample, or one where the second allele is not amplified by the primers. This also applies to DPB1*09:01,10:01 samples.
2.	2. Hazard giving rise to the FSCA
	A customer typed a DPB1*10:01,17:01 sample as DPB1*09:01,17:01 using QTYPE lot E058 due to a false negative reaction in the O560 mix in well O21 on the QTYPE plate. The rFF was 0.74, which was below the threshold of 0.75.

2.	3. Probability of problem arising
	The issue only occurs in DPB1*10:01,17:01 and DPB1*10:01,09:01 samples, and may or may not be below the threshold (depending on instrument-to-instrument variation; reporting customer's rFF was 0.01 below the threshold.)
2.	4. Predicted risk to patient/users
	DPB1*10:01,17:01 and DPB1*09:01,10:01 samples may be incorrectly typed due to the false negative reaction in O21.
2.	5. Further information to help characterise the problem
	Samples typed as DPB1*09:01,17:01 or DPB1*09:01,10:01 by QTYPE should be checked for a near-threshold amplification in position O21 O560. As per the product's intended use, results from typing with QTYPE must not be used as the sole basis for making clinical decisions.
2.	6. Background on Issue
	The rCq range and fluorescence threshold for the mix were established using data from in-house testing of both DPB1*10:01 and DPB*17:01 samples separately. The lower amplification was not observed because a sample with both alleles was not tested.
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: • Samples typed as DPB1*09:01,17:01 or DPB1*09:01,10:01 by QTYPE should be checked for a near-threshold amplification in position O21 O560. • Update to typingkit_QTYPE_20220921.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-Oct-10
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 whereby the threshold for the rFF in the mix in O21 O560 in lots E050, E051, E053, E054, E055, E056, E057, E058, E059, E060 and E061 has been lowered to account for competitive amplification that affects the rFF. The change is in effect starting with the typing kit file Typingkit_QTYPE_20220921.vda	
3	6. By when should the action be completed?	2022-Sep-24
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.