FSN Ref: 2021-03

Date: 2021-06-11

Urgent Field Safety Notice
Olerup QTYPE 11 E047

For Attention of: Users of product Olerup QTYPE 11 lot E047

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)
	0 7340035 52500 4
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. To be used as an aid in determining HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and/or DPB1 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)
	201.701-10
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot E047
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	Increased potential risk for not getting valid DRB results due to qPCR false positive reactions stemming from fluorescent crosstalk on ThermoFisher Viia7 and QuantStudio 6 Flex, 7 Flex and DX systems.

2.	2. Hazard giving rise to the FSCA
	No results or incorrect results generated due to false positive results.
2.	3. Probability of problem arising
	Low
2.	4. Predicted risk to patient/users
	The issue manifests in such way that it is evident for a trained professional that the test is not performing as expected. This issue will manifest as false positive amplifications. The issue is rare, occurs only on certain instruments and only for specific allele combinations present in the sample (refer to the background information in section 2.6 for details). There is low risk to patient safety or health deterioration, due to the role that the generated results play in the context of clinical transplant decision making and the intended use of the product. There is no risk to users.
2.	5. Further information to help characterise the problem
	Although crosstalk between fluorescent channels is mostly corrected by colour compensation, on ThermoFisher instruments supported by Olerup QTYPE 11 there is an increased chance of residual crosstalk from the FAM probe detected in the O560 channel on the outer edges of the PCR plate. This level of crosstalk is rarely enough to lead to a false positive reaction, however on certain instruments the effect is more pronounced and false positives can occur.
2.	6. Background on Issue
	One complaint received from a customer for lot E047 where the assay reported no DRB result. Internal investigation shows that the issue is related to crosstalk. The root cause investigation has been performed. The documented failure and underlying data indicate bleeding of fluorescence signal from the FAM reaction into the O560 channel in well B1 and M3 in samples where reaction for class I allele containing FAM probe was positive and reaction for class II allele containing O560 probe was negative in the same well.
2.	7. Other information relevant to FSCA
	It is possible that in rare circumstances this may occur in other Olerup QTYPE 11 lots manufactured before lot E049.

	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: The Olerup QTYPE 11 kit and SCORE 6 are indicated for use by clinicians trained in molecular biology techniques, working in histocompatibility and immunogenetics laboratories. Regardless of lot used, any suspected false positive reactions (e.g. as highlighted in the tolerance results in SCORE 6) should be manually inspected and evaluated by the user. If called for, the reaction can be excluded, as instructed by the SCORE 6 IFU.

3.	2. By when should the action be completed?	Customer Reply Form to be returned by 2021-06-28
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 Olerup QTYPE 11 plate layout has been modified, with relocation of affected mixes to mitigate fluorescence cross talk. This change was put in place from lot E049.	
3	6. By when should the action be completed?	This change was put in place from lot E049.
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:	Customer/Distributor Reply Form
4.	7. Name/Signature	[redacted] Head of Regulatory Affairs
		[redacted]

	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.