FSN Ref: 2021-01

Date: 2021-02-01

Urgent Field Safety Notice
Olerup QTYPE 11 E044

For Attention of: Users of product Olerup QTYPE 11 lot E044

Contact details (name, e-mail, telephone, address etc.)
Maria Ilar regulatory-se@caredx.com +46 8 508 939 00 Franzéngatan 5 112 51 Stockholm Sweden

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 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 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 E044
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	Increased risk for qPCR curve artefacts such as increased noise levels and more frequently rising baselines, leading to an increased risk of false positive or false negative control reactions.

2.	2. Hazard giving rise to the FSCA
	No results or incorrect results generated due to increased number of false positive and/or false negative control reactions.
2.	3. Probability of problem arising
	High probability for certain kits from lot E044.
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. 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. The device is not to be used as sole basis for clinical decisions and from what has been documented, labs experiencing these failures have reverted to reflex testing with other HLA typing methods normally used as backup in the lab. There is no risk to users.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Feedback and related field data were received from several customers for lot E044. The feedback from customers involved tests that failed to be analysed, since no results were generated, or the generated results were not conclusive and logical from a genetic point of view. Internal investigation shows that the issue is contained within a subset of lot E044. The root cause is under investigation. The documented failures and underlying data indicate a potential PCR reagent stability issue for part of lot E044.
2.	7. Other information relevant to FSCA
	There are no indications that other lots of the device are affected by this issue.

	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: • Do not use product lot E044. • Destroy unused product. • Count the destroyed amount of kit and add this information in the Customer Reply Form.

3.	2. By when should the action be completed?	No further use of Lot E044 after receiving this information. Customer Reply Form to be returned by 2021-02-26
3.	3. Particular considerations for: IVD Yes If data already generated with lot E044 is/has been confirmed by a second typing method, the result could be considered valid. Otherwise, a review of already generated E044 data considering this FSN should take place.	
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 Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	2021-03-31
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	Maria Ilar Head of Regulatory Affairs Maria Ilar

	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.

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2021-01
FSN Date*	2021-02-01
Product/ Device name*	Olerup QTYPE 11
Product Code(s)	201.701-10
Batch/Serial Number (s)	E044

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation			
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number: E044
		N/A	Comments:
☐	No affected devices are available for destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

CareDx AB
Address: Franzéngatan 5, 112 51 Stockholm, Sweden Org.nr. 556550-7257 www.caredx.com

4. Return acknowledgement to sender	
Email	regulatory-se@caredx.com
Postal Address	Franzéngatan 5, 112 51 Stockholm, Sweden
Web Portal	https://labproducts.caredx.com/
Deadline for returning the customer reply form*	2021-02-26

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

CareDx AB
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