



Urgent Field Safety Notice Olerup QTYPE 11 E044

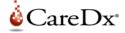
For Attention of: Users of product Olerup QTYPE 11 lot E044

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

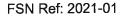
1. Information on Affected Devices*		
1. Device Type(s)		
Olerup QTYPE 11 kits consist of qPCR plates containing pre-aliquoted and dried reaction mixes in each well, together with Master Mix provided in separate vials.		
2. Commercial name(s)		
Olerup QTYPE 11		
3. Unique Device Identifier(s) (UDI-DI)		
0 7340035 52500 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.		
5. Device Model/Catalogue/part number(s)		
201.701-10		
6. Software version		
N/A		
7. Affected serial or lot number range		
Lot E044		
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.			



 No results or incorrect results generated due to increased number of false positive and false negative control reactions. 3. Probability of problem arising High probability for certain kits from lot E044. 4. Predicted risk to patient/users The issue manifests in such way that it is evident for a trained professional that the tes not performing as expected. There is low risk to patient safety or health deterioration, or to the role that the generated results play in the context of clinical transplant deciss making and the intended use of the product. The device is not to be used as sole ba for clinical decisions and from what has been documented, labs experiencing the failures have reverted to reflex testing with other HLA typing methods normally used backup in the lab. There is no risk to users. 5. Further information to help characterise the problem N/A 6. Background on Issue Feedback and related field data were received from several customers for lot E044. feedback from customers involved tests that failed to be analysed, since no results were not conclusive and logical from a genetic profivew. Internal investigation shows that the issue is contained within a subset of lot E044. 				
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		The root cause is under investigation. The documented failures and underlying data		
There are no indications that other lots of the device are affected by this issue.	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.	1. Action To Be Taken by the User*		
		 ☑ Identify Device ☑ Quarantine Device ☑ Return Device 		
		□ On-site device modification/inspection		
		□ Follow patient management recommendations		
		□ Take note of amendment/reinforcement of Instructions For Use (IFU)		
	 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.	
		action be completed ?		
	<u> </u>	Customer Reply Form to be returned by 2021-02-26		
3.	3.	Particular considerations for: IVD		
		Yes		
		It data already generated v	vith lot E044 is/has been confirm	ned by a second typing
			considered valid. Otherwise, a	
		generated E044 data cons	idering this FSN should take pla	ace.
3.	4.	Is customer Reply Require	d?	Yes
	(lf	yes, form attached specifyin	g deadline for return)	
3.	5.	Action Being Taken by the Manufacturer		
		Product Removal	On-site device modification	n/inspection
		Software upgrade	IFU or labelling change	
		Other		
		Provide further details of the a		
3	6.	By when should the	2021-03-31	
		action be completed?		
3.	7		communicated to the patient No	
U.	1.	7. Is the FSN required to be communicated to the patient No /lay user?		
3	0		ovided additional information of	
Ð	о.		ovided additional information su	
	_		-professional user information l	etter/sneet?
		N/A		

	4. Ge	eneral Information
4.	1. FSN Type	New
4.	 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) Author communication to customers.	prity of your country has been informed about this
4.	6. List of attachments/appendices:	Customer/Distributor Reply Form
4.	7. Name/Signature	Maria Ilar
		Head of Regulatory Affairs
	-	Maria llar

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



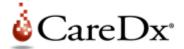
Transmission of this Field Safety Notice

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		
2021-01		
2021-02-01		
Olerup QTYPE 11		
201.701-10		
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: N/A	Lot/Serial Number: E044 Comments:
	No affected devices are available for destruction	Customer to complete or enter N/A	
	Other Action (Define):		
	l 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*			



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	2021-02-26
form*	

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.