Rev 1: September 2018
FSN Ref: FSN 2025-06 FSCA Ref: A-2025-166

Date: 17Dec2025

Urgent Field Safety Notice
Olerup QTYPE 11

For Attention of*: Users of Olerup QTYPE 11

Contact details of local representative (name, e-mail, telephone, address etc.)*
CareDx AB regulatory-se@caredx.com Franzéngatan 5 112 51, Stockholm Sweden

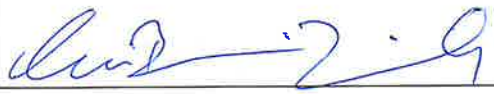
	1. Information on Affected Devices*
1	1. Device Type(s)*
	Olerup QTYPE 11
1	2. Commercial name(s)
	Olerup QTYPE 11
1	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1	4. Primary clinical purpose of device(s)*
	Olerup QTYPE 11 HLA Typing Kits are qualitative in vitro diagnostic tests for the DNA typing of HLA Class I and Class II alleles. 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. The product is intended for use with a validated real-time PCR instrument. The Olerup QTYPE 11 kit is indicated for use by clinicians and laboratory technicians trained in molecular biology techniques, working in histocompatibility and immunogenetics laboratories. 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)*
	201.701-10 201.701-03
1	6. Software version
	N/A
1	7. Affected serial or lot number range
	E073, E074, E075, E076, E077, E078, E079, E080, E081
1	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2	1. Description of the product problem*
	A customer reported that they had a sample that gave discrepant results between Olerup QTYPE 11 and NGS/LinkSeq. NGS results for the sample was DPB1*02:01,165:01 while Olerup QTYPE 11 results were DPB1*02:01,16:01. The mix in position L23 (O560 channel) on the Olerup QTYPE 11 plate was identified as being false positive. In-house testing of the same sample on a similar instrument confirmed the initial results. In both runs, the relative Cq of the amplification was just under the upper cutoff of the range that was set in the typing kit file, indicating a slightly late reaction. The relative Final Fluorescence (rFF) values, while above the threshold, were significantly lower than those seen in tests with true positive samples, but the overall well call was positive based on current file settings.

2	2. Hazard giving rise to the FSCA*
	DPB1*165:01 may be typed as DPB1*16:01 by Olerup QTYPE 11.
2	3. Probability of problem arising
	The problem may arise with samples that are DPB1*165:01.
2	4. Predicted risk to patient/users
	It is anticipated that the discrepancy, if it arises, is easily detected as Olerup QTYPE 11 (according to its intended use) must not be used as the sole basis for making clinical decisions.
2	5. Further information to help characterise the problem
	N/A
2	6. Background on Issue
	The allele motif has a proximal mismatch with the forward primer. The reactivity for the motif was set to negative as it was assumed that the mismatch would negatively affect amplification, however this could not be confirmed at the time of mix development as there was no sample with rare allele DPB1*165:01 available to test.
2	7. Other information relevant to FSCA
	Among the list of associated alleles in well L23 channel O560, the reactivity of DPB1*165:01 has been changed from negative ('-') to questionable ('?') in typing kit file 20251215 for all lots containing the same mix design in order to minimise the risk of the amplification being interpreted as a false positive. The change only impact allele DPB1*165:01 reactivity and no other impact of alleles associated with well L23 channel O560. The change has minimal effect on the intended resolution of the product (low to intermediate) and is not expected to result in common ambiguities.

	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	
	Download the updated typing kit file, Typingkit_QTYPE_20251215.vda, from the CareDx website.	
3.	2. By when should the action be completed?	30Jan2026
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes 30Jan2026
3.	**5. Action Being Taken by the Manufacturer**	
	☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change	

	☒ Other ☐ None CareDx will provide the updated typing kit file, Typingkit_QTYPE_20251215.vda, on the CareDx website.	
3	6. By when should the action be completed?	19Dec2025
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?	
	No Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	CareDx AB
	b. Address	Franzéngatan 5, 112 51, Stockholm
	c. Website address	www.caredx.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	Anna Bereza-Jarocinska Sr. Regulatory Affairs 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.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.