FSN Ref: 2023-02

Date: 2023-02-15

Urgent Field Safety Notice
SSP

For Attention of: Users of product SSP lot 6N9

Contact details (name, e-mail, telephone, address etc.)
Anna Bereza-Jarocinska 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)
	The Olerup SSP kits consist of PCR plates containing pre-aliquoted and dried reaction mixes in each well, together with Master Mix provided in separate vials.
1.	2. Commercial name(s)
	SSP HLA-A low
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)
	Olerup SSP® HLA Typing Kits are qualitative in vitro diagnostic kits for the DNA typing of HLA Class I and HLA Class II alleles. The products are used by trained professionals in medical settings for the purpose of determining HLA phenotype. The source material tested is DNA.
1.	5. Device Model/Catalogue/part number(s)
	101.401-12u, 101.401-48u
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	6N9
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	A total of three customers have reported failure of internal control and HLA-specific amplifications in multiple wells in the Olerup SSP HLA-A low kit lot 6N9. Depending on the location and number of failed wells, interpretation has been affected and tests have needed to be rerun. There is no indication of a recurring pattern/location of the failed wells.
2.	2. Hazard giving rise to the FSCA
	As the product is used to determine HLA phenotype using patient-derived DNA, there is no direct harm to patients. Depending on the location of failed well(s) and level of redundancy of the plate, one or more failed amplifications may lead to a delay in the generation of low resolution HLA-A low results provided by this specific product as the test may need to be rerun.
2.	3. Probability of problem arising
	The frequency of occurrence is currently unknown. The issue has been reported by three customers who have observed tests with anywhere from 2-15 wells with failed internal control amplifications. 30+ tests from lot 6N9 in the CareDx AB warehouse have been tested with no indication of higher number of dropouts than expected for the SSP method.
2.	4. Predicted risk to patient/users

	There is low risk to patient safety or health deterioration as the typing results are not generated when amplification is incomplete. Due to the potential need for re-run of the analysis a delay in results may occur. There is no risk to users.
2.	5. Further information to help characterise the problem
	None
2.	6. Background on Issue
	Three customers have reported failure of internal control and HLA-specific amplifications in multiple wells in the Olerup SSP HLA-A low kit lot 6N9 at a frequency that is higher than what can be expected or explained by the occurrence of random dropouts due to the nature of the method. Because the performance of lot 6N9 cannot be guaranteed and may lead to the delay in generation of HLA-A low resolution results, customers are asked to scrap any remaining tests from this lot. See below for instructions.
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: • Scrap the remaining Olerup SSP HLA-A low lot 6N9 still in your storage and contact your local sales representative for replacement for scrapped kits. • Return Customer/Distributor Reply Form	
3.	2. By when should the action be completed?	01 Mar 2023
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 • Send replacement kits to affected users.	
3	6. By when should the action be completed?	01 Mar 2023
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 to 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.