FSN Ref: 2021-02

Date: 2021-03-26

Urgent Field Safety Notice
SCORE 6

For Attention of: Users of product SCORE 6

Contact details (name, e-mail, telephone, address etc.)
[redacted]

1. Information on Affected Devices*	
1.	1. Device Type(s)
	Software
1.	2. Commercial name(s)
	SCORE 6
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)
	SCORE 6 is intended to be used for the interpretation of test results from QTYPE11 HLA Typing Kits of HLA Class I and Class II alleles.
1.	5. Device Model/Catalogue/part number(s)
	N/A
1.	6. Software version
	All versions up to 6.1.3.0
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	SCORE 6 sometimes incorrectly sets the Cq value to 0 (zero) for calls that have an exponential amplification. This may lead to the software incorrectly excluding alleles that are present in the sample, if the reaction pattern matches an allele combination other than the expected for the sample.
2.	2. Hazard giving rise to the FSCA
	In the worst case, this problem might result in a wrong typing result, leading to a delayed transplant decision. The updated software will exclude well calls where Cq is incorrectly set to zero to avoid wrong typing results.
2.	3. Probability of problem arising
	The probability is low. The issue, where Cq=0 was wrongly assigned, has been reported for 0.035% of tests sold since 2017. In majority of cases, incorrect assignment of Cq to 0 caused 'No result'- the run or HLA type could not be interpreted, or genotype could not be calculated for one or several loci. Wrong typing due to wrongly assigned Cq=0 was reported in 0,0025% of tests sold since 2017.

2.	4. Predicted risk to patient/users
	The patient risk is very low. In majority of the cases reported, incorrect assignment of Cq=0 led to inability of the software to calculate result, not to an incorrect result. 'No result' message will prompt user to repeat the test. In accordance with the Instructions for Use, QTYPE and SCORE 6 must not be used as the sole basis for making clinical decisions, therefore result reported by SCORE 6 will be confirmed by another method.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The incorrect Cq assignment is due to a data processing algorithm in SCORE 6. The service pack SCORE 6.1.3.1 will exclude the wells that have Cq=0 and a positive final fluorescence (i.e. wells with a positive signal that were assigned Cq=0 by the algorithm). Excluding the wells that might be false negatives, might lead to more ambiguous results, but the risk of getting erroneous typing results due to false negatives is removed.
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: Upgrade SCORE 6 software to version 6.1.3.1. SCORE 6 version 6.1.3.1 will be available for download on the CareDx webpage from 2021-04-15. Until then the user should follow the normal test results review procedures.	
3.	2. By when should the action be completed?	Upgrade to SCORE 6 version 6.1.3.1 and return Distributor/Customer Reply Form by 2021-04-30.
3.	3. Particular considerations for: IVD Yes All QTYPE tests should be confirmed by a secondary method.	
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?	2021-04-15
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	[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.