FSN Ref: 2021-06

Date: 2021-10-29

Urgent Field Safety Notice
SCORE 6

For Attention of: Users of product SCORE 6

Contact details (name, e-mail, telephone, address etc.)
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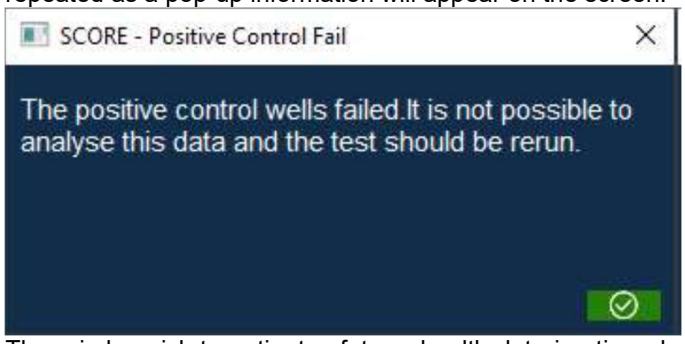
1. Information on Affected Devices*	
1.	1. Device Type(s)
	Software
1.	2. Commercial name(s)
	SCORE 6
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)
	SCORE 6 is intended to be used for the interpretation of test results from QTYPE11 HLA Typing Kits of HLA 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.x.x
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), which is interpreted as a negative call, for curves that have an exponential amplification (i.e., should be positive). This is a known bug with the curve detection algorithm, and the in SCORE 6.1.3.1 the code was updated to exclude HLA wells where this happens. This error may still occur in Positive Control (PC) wells, in which case the test will consider this a PC failure and not allow the user to analyse the results.
2.	2. Hazard giving rise to the FSCA
	In the worst case the PC wells will fail, and the user will need to rerun the test. This problem might lead to a delayed typing result, and a delayed transplant decision.
2.	3. Probability of problem arising
	The probability of occurrence is low. The issue, where Cq=0 was wrongly assigned to PC, and this in turn resulted in the need to repeat the run, has been reported for 0,018% of tests sold since lot E036. The very low frequency indicates a low probability for this error to occur.
2.	4. Predicted risk to patient/users
	In cases where too many PC wells have Cq=0 erroneously assigned the run needs to be repeated, but this error will not lead to an incorrect result.

	The user is aware that the software is unable to calculate HLA result and that the run needs to be repeated as a pop-up information will appear on the screen.  There is low risk to patient safety or health deterioration, due to low occurrence of this error, as well as due to the role that the generated results play in the context of clinical transplant decision making and the intended use of the product. There is no risk to users.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	One customer reported failure in run due to Cq=0 was assigned to two positive PC wells. PC failure will prevent customer analysing data, therefore there is no risk of mistyping, however the customer will need to re-run the plate. Incorrect assignment of Cq value to 0 (zero), which is interpreted as a negative call, for calls that have an exponential amplification (should be positive) is a known bug with SCORE 6 versions up to 6.1.x.x. SCORE 6.1.3.1 service pack was released to mitigate the risk of this bug producing negative calling for HLA-detecting wells. The mitigation in SCORE 6.1.3.1 changes the call from “negative” to “excluded”, when “negative” call was assigned due to this bug. The mitigation was not implemented for PC wells, since it is, by design, already part of the PC algorithm to fail the test if there are too many exclusions, i.e. excluded PC wells would still result in failed run and need for retesting.
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: Return signed Customer/Distributor Reply Form	
3.	2. By when should the action be completed?	2021-11-12
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 Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	With the release of SCORE 6 version 6.2.
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	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.