

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.)
<p>Maria Ilar regulatory-se@caredx.com +46 8 508 939 00 Franzégatan 5 112 51 Stockholm Sweden</p>

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.

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	Franzégatan 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
		

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>