GeneProof

Rev 2: February 2020

FSN Ref: FSN 00323

FSCA Ref: FSCA 00323

Date: 2023-04-27

Field Safety Notice

myCROBE® Fully Automated Instrument

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

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Field Safety Notice (FSN)

myCROBE® Fully Automated Instrument

Incorrect positive results of negative samples

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	In vitro diagnostic medical device
1.	2. Commercial name(s)*
	myCROBE® Fully Automated Instrument
1.	3. Unique Device Identifier(s) (UDI-DI)
	859569630052QL
1.	4. Primary clinical purpose of device(s)*
	The device is intended for a fully automated analysis of clinical samples from extraction to results evaluation. This system is intended for diagnostic processes including screening, monitoring, diagnostics and aid to diagnosis. The intended users are trained professionals in clinical laboratories. The device is a fully automated system, which covers the entire process from NA extraction, PCR setup (including PCR plate sealing) and PCR amplification to automatic result evaluation. The device is intended to be used in combination with the myCROBE/croBEE 2.0 Universal Extraction Kit followed by the GeneProof MC PCR diagnostic kit.
1.	5. Device Model/Catalogue/part number(s)*
	MC100
1.	6. Software version
	2.2.2.
1.	7. Affected serial or lot number range
	TR 05376; TR 05161; TR 05378; TR 05381
1.	8. Associated devices
	• myCROBE/croBEE 2.0 Universal Extraction Kit • GeneProof MC PCR kits

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Based on a customer complaint, the possibility of false positive results was identified in case of an exceptionally high positive neighbouring sample in the same run. Next to the high positive sample, a low positive sample was found which was not confirmed by any other method.
2.	2. Hazard giving rise to the FSCA*
	The possibility of a false positive results in the case of an exceptionally high positive neighbouring sample in the same run.
2.	3. Probability of problem arising
	Low, depending on the occurrence of a significantly high positive sample (low Ct values approximately Ct≤20).
2.	4. Predicted risk to patient/users
	False positive results of negative samples or incorrect (higher) quantification of weakly positive samples. In the worst case, if the clinical picture of the patient is ignored, the patient could be inadequately treated.
2.	5. Further information to help characterise the problem
	The issue seems to be related to the carryover between high positive and negative samples on myCROBE (=> high number of false positives).

	This is probably an occurrence of cross-contamination caused by malfunctioning of the myCROBE instrument. Cross-contamination could cause incorrect evaluation of negative samples. The measure concerns 3 users of instruments installed in the Czech Republic and 1 user in Switzerland.
2.	6. Background on Issue
	The root cause is now under investigation.
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 Suspension of nucleic acid extraction and microbiological PCR testing on the myCROBE device and suspension of the release of patient results. This measure does not apply to myCROBE thrombotic mutation testing.	
3.	2. By when should the action be completed?	Effective immediately
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes, if discrepancies between clinical picture and test results are found. Despite this, it is recommended to review the previous positive results if a strongly positive sample with Ct≤20 occurred in the run(s). False positive results (if any) are expected to be rare.	
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	

	In solution. GeneProof is conducting further investigations to implement control measures to prevent the reported problem.	
3.	6. By when should the action be completed?	Without undue delay.
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. 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	**GeneProof a.s.**
	b. Address	**Vídeňská 101/119, Dolní Heršpice, 619 00 Brno, Česká Republika**
	c. Website address	**www.geneproof.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	**Kamil Šplíchal** **QA/RA Director**
		Mgr. Kamil Šplíchal Podepsal Mgr. Kamil Šplíchal DN: cn=Mgr. Kamil Šplíchal, c=CZ, email=kamil.splichal@geneproof.com Datum: 2023.04.27 18:05:16 +02'00'

	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.