GeneProof

Rev 2: February 2020

FSN Ref: FSN 00123

FSCA Ref: FSCA 00123

Date: 2023-03-03

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.

GeneProof

Field Safety Notice (FSN)
myCROBE® Fully Automated Instrument
Incorrect negative results of positive 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
	1.0.02
1.	7. Affected serial or lot number range
	TR 05376; TR 05161, 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*
	Incorrect negative results of positive samples using the fully automated myCROBE® instrument due to a bug in software version 1.0.02
2.	2. Hazard giving rise to the FSCA*
	Following a customer complaint, a bug in the myCROBE software was identified that could cause incorrect evaluation of negative samples. For this reason, it is necessary to upgrade the software to version 1.0.13. Until the software is upgraded, it is necessary to check the raw data of the negative samples obtained in the myCROBE report before issuing the results.
2.	3. Probability of problem arising
	Low
2.	4. Predicted risk to patient/users
	Incorrect negative results of positive samples
2.	5. Further information to help characterise the problem
	The measure affects two users of devices installed in the Czech Republic and one in Switzerland. For all negative results a raw data check is needed. We recommend sending the raw data by the user/customer to support@geneproof.com, who will immediately verify the correctness of the evaluation of the negative results. The results of the analyses can

	only be released after the data has been checked in cooperation with Geneproof Support a.s. A GeneProof service technician will contact the laboratories concerned in the near future to set up a date to reinstall the software.
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 Send the data to support@geneproof.com to verify the accuracy of the negative results. Analytical results can only be released after checking the data in collaboration with Support Geneproof. This should be done until the software is reinstalled.	
3.	2. By when should the action be completed?	2023-03-15
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes If inconsistencies between the clinical diagnosis and test results were observed. In such instances the negative results should be re-examined by reviewing the raw data. False negative results (if any) are expected to have been a rare occurrence.	
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 SW version 1.0.02 will be upgraded to version 1.0.13. Until the software is reinstalled, send the acquired data to *support@geneproof.com* to verify the correctness of the evaluation of negative results. The results of the analyses can only be released after checking the data in cooperation with Support Geneproof.	
3.	6. By when should the action be completed?	2023-03-15

GeneProof

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*	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN 00123
4.	3. For Updated FSN, key new information as follows:	
	Adding a serial number and another affected customer	
4.	4. Further advice or information already expected in follow-up FSN? *	N/A
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: 2023.03.03 09:44:13 +01'00'

	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.