Rev 2: February 2020

FSN Ref: FSN 00124

FSCA Ref: FSCA 00124

Date: 2024-10-24

Field Safety Notice

GeneProof Aspergillus PCR Kit

False negative results may occur in bronchoalveolar lavage (BAL) specimens due to as of now unidentified interferences

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)

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	In vitro diagnostic medical device
1.	2. Commercial name(s)*
	GeneProof Aspergillus PCR Kit
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The kit is an in vitro nucleic acid amplification test intended for detection of *Aspergillus spp.* (*A. fumigatus, A. flavus, A. niger, A. oryzae, A. candidus, A. foetidus, A. nidulans, A. ustus, A. versicolor, A. wentii, A. clavatus, A. niveus*) and *A. terreus* in the clinical specimens: BAL, CSF, plasma, serum, sputum, whole blood. The kit is intended to use in combination with a manual or automated extraction system. The kit is designed for human in vitro diagnostics and provides qualitative detection. The kit is intended for diagnostics, and aid for diagnosis and it is designed for professional use in laboratories with trained staff. The target population is the EU population. The intended testing population is immunocompromised individuals.
1.	5. Device Model/Catalogue/part number(s)*
	ASP/ISEX/025; ASP/ISEX/100
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	2438657; 2438658; 2438674; 2438843; 2439133; 2439332; 2439541
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	In the framework of the post-market surveillance, we tested samples of *Aspergillus niger* and *Aspergillus fumigatus* in BAL specimens. The results obtained showed that the above listed batches of the product may have reduced fluorescence in the FAM channel and shifted Ct values, which could cause false negative results for this type of specimen.
2.	2. Hazard giving rise to the FSCA*
	The possibility of false negative results in the testing of some types of BAL samples, caused by a decrease in fluorescence and a shift in Ct values in the listed batches due to as of now unidentified interferences.
2.	3. Probability of problem arising
	Medium
2.	4. Predicted risk to patient/users
	Serious reversible injury
2.	5. Further information to help characterise the problem
	Invasive aspergillosis is one of the leading causes of mortality in immunocompromised patients. Early diagnosis and appropriate treatment are crucial for patient survival. Not only PCR, but also

	serological, radiological, bronchoscopic, and microscopic methods are used to diagnose aspergillosis. In high-risk patients, a combination of PCR and serology is recommended; the use of radiology, bronchoscopy and microscopy further reduces this risk. [1, 2, 3] **Due to the guideline [4], sole PCR from BAL is not a recommended method in immunocompromised patients under suspicion of having aspergillosis. Moreover, a treatment with voriconazole is initiated based on suspicion. A chance of a doctor ceasing a voriconazole treatment based on a false-negative PCR result is very low.** [1] https://www.idsociety.org/practice-guideline/aspergillosis/#RecommendationsAbridged [2] https://www.tandfonline.com/doi/abs/10.2217/fmb.15.140 [3] https://journals.asm.org/doi/full/10.1128/jcm.00818-16 [4] Patterson, T. F., Thompson III, G. R., Denning, D. W., Fishman, J. A., Hadley, S., Herbrecht, R., ... & Bennett, J. E. (2016). Practice guidelines for the diagnosis and management of aspergillosis: 2016 update by the Infectious Diseases Society of America. Clinical infectious diseases, 63(4), e1-e60.
2.	6. Background on Issue
	The root cause is now under further 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 **Confirmation from end users (laboratories) whether they have the batch in stock,** marking it and then properly disposing of it (including photographic documentation), or sending it back to the manufacturer. Such kits will be compensated by the manufacturer.	
3.	2. By when should the action be completed?	**15.11.2024**
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes, if there are discrepancies between the clinical picture and the test results from the BAL samples. We recommend reviewing previous negative patient results if the patient's clinical picture does not correspond to the result obtained.	
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 The affected batches of product have been quarantined and may not be further distributed. The root cause has not yet been identified. GeneProof is conducting further investigation to implement the necessary corrective actions to prevent the reported issue.	
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 Podepsal Mgr. Kamil Šplíchal DN: cn=Mgr. Kamil Šplíchal, c=CZ, email=kamil.splichal@geneproof.com Datum: 2024.10.25 14:22:33 +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. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and follow-up for a period consistent with applicable legislation 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.

*Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.*