Rev 2: February 2020

FSN Ref: FSN 00623

FSCA Ref: FSCA 00623

Date: 2023-11-23

Field Safety Notice

GeneProof Enterovirus PCR Kit

False positive results due to possible non-specificities associated with the differentiation of rhino/entero-positive samples

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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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	In vitro diagnostic medical device
1.	2. Commercial name(s)*
	GeneProof Enterovirus PCR Kit
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	Kit is an in vitro nucleic acid amplification test intended for measurement and detection of Enteroviruses (Enterovirus species A-D) by real-time polymerase chain reaction (PCR) method. The clinical specimens used for the detection are: CSF, swab and stool. PCR kit can be used in combination with a manual or automated extraction system. The kit is designed for human in vitro diagnostics and provides both qualitative and quantitative detection. The kit is intended for diagnostics and aid to diagnosis or monitoring test and it is designed for professional use in laboratories with trained staff. The target population is the EU population. The intended testing population is general population.
1.	5. Device Model/Catalogue/part number(s)*
	EV/ISEX/025; EV/ISEX/100
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	2337650; 2337663; 2337829; 2338053; 2338146; 2338277; 2336718; 2336741; 2337261; 2337300; 2337306; 2336207; 2336239; 2336366; 2336623; 2336666; 2336682; 2336762; 2336795; 2336793; 2336852; 2336920; 2336950; 2336967; 2337126; 2337179; 2337388; 2337447; 2337533; 2337632; 2337772; 2337797; 2337953; 2338064; 2338143; 2338163 *Note:* *Considering the 12-month shelf-life of the kit, we list all batches produced in 2023.*
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Based on customer feedback, we investigated the potential non-specificities associated with the GeneProof Enterovirus PCR Kit with respect to the differentiation of rhino/entero-positive samples. As part of the PMS, we performed a control *in silico* analysis with so far known rhinovirus sequences. Unfortunately, we obtained results indicating that some rhinoviruses can lead to false positive results for enteroviruses (6 of 165 known rhinoviruses).

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2.	2. Hazard giving rise to the FSCA*
	False positive results - due to sequence similarity with rhinoviruses, it cannot be excluded that the GeneProof Enterovirus PCR Kit shows cross-reactivity with rhinoviruses B5, B42, B99, C3, C39 and C43.
2.	3. Probability of problem arising
	Medium
2.	4. Predicted risk to patient/users
	False positive results for enterovirus due to cross-reactivity with rhinoviruses B5, B42, B99, C3, C39 and C43 may occur. There is no uniform antiviral treatment for enterovirus. It is treated symptomatically. If the patient has complications, cases are considered individually, and a single PCR result is not sufficient.
2.	5. Further information to help characterise the problem
	-
2.	6. Background on Issue
	Root cause in 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 If the test is positive for enterovirus, inform the treating physician that cross-reactivity with rhinoviruses B5, B42, B99, C3, C39 and C43 may occur; so that they can take this possibility into account when considering further testing and treatment.	
3.	2. By when should the action be completed?	**15.12.2023**
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No There is no uniform antiviral treatment for enterovirus. It is treated symptomatically. If the patient has complications, cases are considered individually, and a single PCR result is not sufficient.	
3.	4. Is customer Reply Required? *	**YES**

	(If yes, form attached specifying deadline for return)	
3.	**5. Action Being Taken by the Manufacturer***	
	☐ Product Removal ☐ Software upgrade ☒ Other	☐ On-site device modification/inspection ☐ IFU or labelling change ☐ None
	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**
		Mgr. Kamil Šplíchal Podepsal Mgr. Kamil Šplíchal DN: cn=Mgr. Kamil Šplíchal, c=CZ, email=kamil.splichal@geneproof.com Datum: 2023.11.23 08:58:25 +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.