SEROSEP	Title	Document ID	REG SOP 03 FORM 03
	Field Safety Notice	Revision	03
		Responsibility:	**Regulatory**
FSN Ref: FSN 2023-001		Issue Date:	**01 Dec 2022**
FSCA Ref: FSCA 2023-001/ FSCA 2023-001-UK1/ FSCA 2023-001-UK3	*Derived from Field Safety Notice template Rev 2: February 2020*		

Date: 2023.01.26

Field Safety Notice
EntericBio Viral Panel 1/EntericBio Viral Panel 3

For Attention of*:Medical Laboratory Scientists, distributors

Contact details of local representative (name, e-mail, telephone, address etc.)*
Serosep Ltd., Annacotty Business Park, Annacotty, Limerick, Ireland. www.serosep.com Technical support Email: support@serosep.com Tel: +353 61 358190

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	Field Safety Notice	Revision	**03**
		Responsibility:	**Regulatory**
FSN Ref: FSN 2023-001		Issue Date:	**01 Dec 2022**
FSCA Ref: FSCA 2023-001/ FSCA 2023-001-UK1/ FSCA 2023-001-UK3	*Derived from Field Safety Notice template Rev 2: February 2020*		

Field Safety Notice (FSN)
EntericBio Viral Panel 1/EntericBio Viral Panel 3
Inaccuracy in IFU related to Sapovirus Genogroup V

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Non-sterile, in-vitro diagnostic PCR test for viral gastroenteritis in liquid stool samples
1.	2. Commercial name(s)*
	EntericBio Viral Panel 1, EntericBio Viral Panel 3
1.	3. Unique Device Identifier(s) (UDI-DI)
	053 9151387 924 1, 053 9151387 926 5
1.	4. Primary clinical purpose of device(s)*
	The EntericBio Viral Panel 1 assay is a molecular diagnostic test for the simultaneous detection of Rotavirus A, Adenovirus F40/F41 and Sapovirus from human stool samples. The assay is intended for use by laboratory scientists in a clinical laboratory setting. The EntericBio Viral Panel 3 assay is a molecular diagnostic test for the simultaneous detection of Rotavirus A, Adenovirus F40/F41, Sapovirus, Astrovirus and Norovirus (Genogroup I and Genogroup II) from human stool samples. The assay is intended for use by laboratory scientists in a clinical laboratory setting.
1.	5. Device Model/Catalogue/part number(s)*
	EBVP1, EBVP3

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	An inaccuracy in the instructions for use was identified following review of external quality assurance (EQA) data. Section 13.1 of the instructions for use correctly shows that Sapovirus genogroup V is not included in the inclusivity of the assay. However, Section 12.3 of the instructions for use inaccurately claims to detect Sapovirus genogroup V in the Target Interpretation section.
2.	2. Hazard giving rise to the FSCA*
	The device will not detect a Sapovirus positive sample in the event that the strain is part of Genogroup V. This genotype is genetically different from the other Sapoviruses and is not inclusive in the design of the Serosep Assay V1 included in both EntericBio Viral Panel 1 and EntericBio Viral Panel 3 kits. Although the prevalence may not be high, it has recently begun to be included in EQA panels to increase awareness of the strains.
2.	3. Probability of problem arising
	Prevalence of this genogroup of Sapovirus is not high so there is a low probability of the problem of false negatives arising.

2.	4. Predicted risk to patient/users
	There is a low probability of patient harm from this issue due to the low prevalence of Sapovirus genogroup V.
2.	5. Background on Issue
	Following review of internal results for the QCMD EQA scheme and feedback from customers on the false negative result for a Sapovirus EQA sample in the 2022 distribution, the IFU was reviewed and the erroneous addition of Sapovirus genogroup V in the Result Interpretation section was identified. In silico analysis of 12 strains of Sapovirus GV and wet testing of the synthetic Sapovirus GV sequence in Assay V1. All of this testing confirmed that Assay V1 (component assay of EntericBio Viral Panel 1 and EntericBio Viral Panel 3) does not detect Sapovirus GV.

	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 Provide further details of the action(s) identified.	
3.	2. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Due to the low prevalence of the Sapovirus genogroup V strains and that Sapovirus causes a self-limiting gastroenteritis, follow-up or retrospective review should not be required.	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer***	
	☐ Product Removal ☐ Software upgrade ☐ Other ☐ On-site device modification/inspection ☒ IFU or labelling change ☐ None	

	Section 12.3 has been updated to state that Genogroup V is not detected. A limitation has also been added to Section 15.0 to state the same.	
3.	5. By when should the action be completed?	Updated IFU accompanies this FSN
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Serosep Limited
	b. Address	Annacotty Business Park, Limerick, V94 FF83
	c. Website address	www.serosep.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	SMD 09 (Rev 02), SMD 11 (Rev 02), REG SOP 03 FORM 04 (Customer)/REG SOP 03 FORM 05 (Distributor)
4.	6. Name/Signature	Dermot Scanlon, CEO 26 Jan 2023

	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.