Date: 2026.07.07

Field Safety Notice

EntericBio®Viral Panel 1, EntericBio Viral Panel 2, EntericBio®Viral Panel 3

For Attention of*:Hospital Stores, Theatre Staff, Medical Laboratory Scientists, Distributors

Contact details of local representative (name, e-mail, telephone, address etc.)*
Serosep Limited, **Annacotty Business Park,** **Annacotty,** **Limerick,** **Ireland.** **Email: *support@serosep.com*** **Tel:+353 61358190** **www.serosep.com**

Field Safety Notice (FSN)

EntericBio®Viral Panel 1, EntericBio Viral Panel 2, EntericBio®Viral Panel 3

EntericBio® Viral Panel pouches are not fully heat sealed

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 2, EntericBio®Viral Panel 3
1.	3. Unique Device Identifier(s) (UDI-DI)
	053 9151387 924 1 - EntericBio®Viral Panel 1 053 9151387 925 8 - EntericBio®Viral Panel 2 053 9151387 926 5 - EntericBio®Viral Panel 3
1.	4. Primary clinical purpose of device(s)*
	The EntericBio® Viral Panel 1 assay is a semi-automated, one strip molecular diagnostic test for direct, qualitative detection of nucleic acids from Rotavirus A, Adenovirus F40/F41 and Sapovirus in human stool samples. The EntericBio® Viral Panel 2 assay is a semi-automated, one strip molecular diagnostic test for direct, qualitative detection of nucleic acids from Astrovirus and Norovirus (Genogroup I and Genogroup II) in human stool samples. The EntericBio® Viral Panel 3 assay is a semi-automated, two strip molecular diagnostic test for direct, qualitative detection of nucleic acids from Rotavirus A, Adenovirus F40/F41, Sapovirus, Astrovirus and Norovirus (Genogroup I and Genogroup II) in human stool samples. The assays are intended for use with liquid/loose stool samples from symptomatic patients with suspected acute gastroenteritis of viral origin.
1.	5. Device Model/Catalogue/part number(s)*
	EBVP1, EBVP2, EBVP3
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Any lots listed below **dispatched from Serosep prior to 19th June 2026 only:** Associated EntericBio Viral Panel 1 Assay kits are as follows:

Kit	Lot number	Expiry Date
EBVP1	24077	28-12-2026
EBVP1	24300	28-12-2026

EBVP1	24569	28-01-2027
EBVP1	25689	28-08-2027

Associated EntericBio Viral Panel 2 Assay kits are as follows:

Kit	Lot number	Expiry Date
EBVP2	24033	28-12-2026
EBVP2	24299	28-12-2026
EBVP2	24425	28-12-2026
EBVP2	24674	28-02-2027
EBVP2	24676	28-05-2027
EBVP2	24848	28-06-2027
EBVP2	25045	28-07-2027
EBVP2	25178	28-07-2027
EBVP2	25306	28-08-2027
EBVP2	25486	28-09-2027
EBVP2	25659	28-10-2027
EBVP2	25763	28-10-2027
EBVP2	26070	28-12-2027
EBVP2	26302	28-01-2028
EBVP2	26369	28-01-2028
EBVP2	23030	28-05-2026 (Expired)
EBVP2	23132	28-06-2026 (Expired)
EBVP2	23224	28-06-2026 (Expired)
EBVP2	23457	28-09-2026
EBVP2	23590	28-09-2026
EBVP2	23708	28-10-2026
EBVP2	23741	28-10-2026
EBVP2	23320	28-08-2026
EBVP2	23400	28-08-2026
EBVP2	25877	28-11-2027

Associated EntericBio Viral Panel 3 Assay kits are as follows

Kit	Lot number	Expiry Date
EBVP3	24034	28-12-2026
EBVP3	24082	28-12-2026
EBVP3	24301	28-12-2026
EBVP3	24492	28-12-2026

EBVP3	24426	28-12-2026
EBVP3	24649	28-01-2027
EBVP3	24675	28-03-2027
EBVP3	24906	28-03-2027
EBVP3	25305	28-05-2027
EBVP3	24846	28-03-2027
EBVP3	25046	28-07-2027
EBVP3	25183	28-07-2027
EBVP3	25421	28-08-2027
EBVP3	25474	28-08-2027
EBVP3	25487	28-08-2027
EBVP3	25732	28-08-2027
EBVP3	25762	28-08-2027
EBVP3	26196	28-11-2027
EBVP3	26168	28-08-2027
EBVP3	26370	28-01-2028
EBVP3	25878	28-11-2027
EBVP3	23131	28-05-2026 (Expired)
EBVP3	23133	28-06-2026 (Expired)
EBVP3	23225	28-06-2026 (Expired)
EBVP3	23399	28-06-2026 (Expired)
EBVP3	23456	28-09-2026
EBVP3	23589	28-09-2026
EBVP3	23709	28-10-2026
EBVP3	23742	28-10-2026
EBVP3	23927	28-10-2026
EBVP3	23031	28-05-2026 (Expired)

Any of the above lots **dispatched after 19th June 2026 are not subject to this FSN.**

Within context of the FSCA eg for IVD reagents and platforms.

2. Reason for Field Safety Corrective Action (FSCA)*

2.	1. Description of the product problem*
	Manufacturing Operator Error: During packaging of the EntericBio® Viral Panel pouches, the operator did not follow the approved Standard Operating Procedure (SOP), resulting in pouches not being fully heat sealed. This led to incomplete package seals. The issue

	was identified as an operator error due to non-compliance with the established manufacturing procedure.
2.	2. Hazard giving rise to the FSCA*
	The risk is that the pouches are not fully heal sealed causing invalid results and increase number of IAC failures. The IFU instructs the user that samples with failed IACs should be retested from the original sample. Repeat testing may lead to delayed treatment and/or delayed patient/ ward management. The Instructions for Use (IFU) for the EntericBio® Viral Panel assays (SMD 09, SMD 10, and SMD 11) state that: • In cases of multiple IAC failures, users should contact the manufacturer. • Assay pouches, component vials, or consumables that are damaged or show signs of deterioration must not be used. Per instructions in Training Manual EBRT APP 02, prior to testing, strips are gently tapped and visually inspected to ensure pellet is present at the bottom of the well. Once the test is performed and analysed as per the instructions for use, there is no risk of incorrect results being reported.
2.	3. Probability of problem arising
	The probability of this issue occurring is low. Based on the investigation, the estimated rate of occurrence is approximately 7.6% within the affected lot numbers released prior to 19th June 2026. Lot numbers released after 19th June 2026 are not affected by this Field Safety Notice.
2.	4. Predicted risk to patient/users
	An increase in Internal Amplification Control (IAC) failure rates may result in invalid test results and necessitate repeat testing of patient samples. This may lead to a delay in reporting patient results. The Internal Amplification Control (IAC) is lyophilized into each reaction well of the EntericBio® Viral Panel 3 assay strip and is designed to monitor for PCR inhibition as well as reagent or amplification failure for each sample tested. The Instructions for Use (IFU) for the EntericBio® Viral Panel assays (SMD 09, SMD 10, and SMD 11) state that: • In cases of multiple IAC failures, users should contact the manufacturer. • Assay pouches, component vials, or consumables that are damaged or show signs of deterioration must not be used. • Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. The optional UgenTec FastFinder software (EntericBio® Viral Panel plug-in) automatically analytes all IAC results before reporting patient results. Per IFU: "*Samples with failed IAC(s) will be reported by the software as "Invalid. Inhibitory sample or reagent failure. Repeat the sample using a new test." These samples should be*

	considered invalid and re-tested from the remaining faecal specimen(s) within the timeframe defined for the specimen stability" Clinical laboratories using LC480 II software are trained in the interpretation of results. In accordance with the IFU: *"A true negative sample must have a positive result for the internal amplification control. Negative samples that have a failed internal control result should be retested from the original sample. If the sample is positive for any of the target organisms in the corresponding well, the internal control result is dispensable due to competition in the reaction".* Provided testing is performed and interpreted in accordance to the IFU, failed IACs are identified by the software and reported as invalid result and samples should be re-tested. The primary clinical consequence is a delay in obtaining and reporting the final result due to repeat testing. The likelihood of harm occurring is unlikely, but possible, if assay pouches that are not fully heat-sealed are used without following the IFU. The severity of the injury or adverse health outcome is limited (Transient, self limiting illness or minor injury). The predicted risk of this hazard to the patient or user is low.
2.	5. Further information to help characterise the problem There is a possibility that some EntericBio® Viral Panel assay pouches may not have been correctly heat sealed. Please refer to images below:  

	Please be vigilant when opening the assay pouches and if a gap is noted on the opposite side, please do not use the strips in the pouch and contact support@serosep.com for further assistance.
2.	6. Background on Issue
	NCP 250 was raised on 19 June 2026 following the identification of improperly heat-sealed pouches of the EntericBio® Viral Panel assays. The issue was first identified in EntericBio Assay V2 PCR Test Pouches (Product Code: EBRTASSAY17; Batch Number: 2EB260401). The impacted pouches were used for EntericBio Viral Panel 3 kits with lot number 26370. Customers who had received the affected batch were notified immediately, and the batch was quarantined. As a precautionary measure, all batches of the EntericBio® Viral Panel assays were quarantined and evaluated. During this assessment, a small number of additional lots were identified as containing pouches with incomplete seals. A Technical Bulletin (SER-TB-2026-04) was issued on 22 June 2026, advising all customers to inspect assay pouches for incomplete seals before use. The bulletin included representative images to assist users in identifying affected pouches. Following the investigation, 100% inspection of all EntericBio® Viral Panel assay batches was performed. Any pouches identified with incomplete or open seals were removed and the affected batches were reworked prior to release. The investigation concluded that the root cause was manufacturing operator error. During the manufacturing process for the EntericBio® Viral Panel pouches, the operator did not follow the approved Standard Operating Procedure (SOP), resulting in pouches that were not fully sealed. This process deviation led to incomplete package seals.
2.	7. Other information relevant to FSCA
	This FSCA does not impact any other EntericBio® Assays.

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 The lot numbers listed in this Field Safety Notice (FSN) may contain pouches that may not have been correctly heat-sealed.

	This issue is limited to the batch numbers identified above that were dispatched before 19 June 2026. EntericBio® Viral Panel assays dispatched on or after 19 June 2026 are not affected by this Field Safety Notice. If any assay pouch is identified as being open or not fully heat sealed prior to use, it should be quarantined and not used for testing**.** Serosep should be contacted for appropriate action.	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No No patient follow up is required: Once the test has been performed and analysed in accordance with the Instructions for Use (IFU), samples with an Internal Amplification Control (IAC) failure are identified by the software and reported as invalid result and should be re-tested. The primary clinical consequence is a delay in obtaining and reporting the final patient result due to IAC failure and the need for repeat testing.	
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 A Field Safety Corrective Action and this Field Safety Notice have been created to inform customers that the lot numbers listed above which were dispatched prior to 19th June 2026 may have an increased occurrence of incorrectly heat-sealed assay pouches. Serosep have performed 100% inspection of all EntericBio® Viral Panel assay batches. Any pouches identified with incomplete or open seals were removed and the affected batches were reworked prior to release. This issue only affects EntericBio® Viral Panel assays dispatched before 19th June 2026. The issue is being further investigated through Serosep's Quality Management System to prevent reoccurrence.	

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, Annacotty, Limerick, Ireland
	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. Name/Signature	Grazyna Olewinska, Regulatory Manager, Deputy PRRC
		Signed by Grazyna Olewinska Grazyna Olewinska | I approve this document 07-Jul-26 | 5:09:27 PM BST BB1E747BE1EB4A9298F2C71101D4C0BA

	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.