Fannin Ltd Galway

Rev 1: September 2018
FSN Ref: DCCV-NC00862 FSCA Ref: DCCV-NC00862

Date: 03/04/2019

Urgent Field Safety Notice

W11049 Blood agar No. 2 + Horse Blood, lot number 1984301033
W11310 Fastidious Anaerobic Agar + Nat, lot number 0124301134
W11326 Staph/Strep Selective Agar Modified, lot number 1284302934

For Attention of: Medical Scientists

Contact details of local representative (name, e-mail, telephone, address etc.)*
Irene Slevin, irene.slevin@fannin.eu, 01 290 7204, Fannin Ltd Galway, I.D.A. Industrial Estate, Ballybrit Upper, Galway

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Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	W11049 Blood agar No 2 + Horse Blood, aseptically dispensed device W11310 Fastidious Anaerobic Agar + Nat, aseptically dispensed device W11326 Staph/Strep Selective Agar Modified, aseptically dispensed device
1.	2. Commercial name(s)
	As above
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	W11049 is used as a general-purpose medium enriched with Horse Blood, suitable for the isolation of most organisms including many fastidious anaerobes of clinical significance. W11310 is a selective medium for the isolation of non-sporing anaerobes particularly anaerobic cocci from clinical specimens. W11326 is a selective medium for staphylococci and streptococci
1.	5. Device Model/Catalogue/part number(s)*
	As above
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	W11049, lot number1984301033 W11310, lot number 0124301134 W11326, lot number 1284302934
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Fungal contamination has been found in sterility samples in the above lots at 20-25C and 30-35C. The contamination is presenting as a grey fungal growth after samples were incubated for 96 hours.
2.	2. Hazard giving rise to the FSCA*
	Contamination could interfere with the growth of the target organisms and/or with colony isolation.
2.	3. Probability of problem arising
	The probability of erroneous results is low as incubation of QC controlled strains showed expected growth and morphology when incubated for 24 hours at 35-37C
2.	4. Predicted risk to patient/users
	Low
2.	5. Further information to help characterise the problem
	N/A

2.	6. Background on Issue
	Each batch listed above had horse blood added. For investigative purposes blood free packs are taken from the start of the batch prior to the addition of the horse blood. These plates are incubated at 30-35C for 14 days. As of 01/04/2019, 11 days post-date of dispensing there is no contamination present on these blood free plates.
2.	7. Other information relevant to FSCA
	The supplier of the horse blood was informed of the contamination found in batches using the same lot number of horse blood. We are currently waiting for their sterility test results. The contaminant has been sent to an independent laboratory for identification.

	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. By when should the action be completed?	11/04/2019
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Test results to be reviewed by the appropriate technical expert Provide further details of patient-level follow-up if required or a justification why none is required	
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 Root cause analysis is ongoing	
3	6. By when should the action be completed?	11/05/2019
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?	
	No	

	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	**Fannin Ltd Galway**
	b. Address	**I.D.A. Industrial Estate, Ballybrit Upper, Galway**
	c. Website address	**www.lipdiagnostic.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. The HPRA	
4.	9. List of attachments/appendices:	**N/A**
4.	10. Name/Signature	**Irene Slevin**

	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.