200 Cooper Avenue North
Saint Cloud, Minnesota 56303 USA
www.microbiologics.com

FSN Ref: 2020006 FSCA Ref: N/A

Date: 08/10/2020

Urgent Field Safety Notice

01245P Klebsiella pneumoniae derived from NCTC 13439

For Attention of*: Clinical Laboratory managers and lab technicians

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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Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Unassayed quality control material for microbiology assays.
1.	2. Commercial name(s)
	01245P Klebsiella pneumoniae derived from NCTC 13439
1.	3. Unique Device Identifier(s) (UDI-DI)
	01245P UDI: 20845357040446
1.	4. Primary clinical purpose of device(s)*
	KWIK-STIK™ microorganisms are intended to be used as controls to verify the performance of assays, reagents or media that are intended to be used in microbial testing for the detection and identification of a cultured microorganism isolate. Each KWIK-STIK contains a qualitative lyophilized microorganism pellet, ampoule of hydrating fluid and inoculating swab. Everything you need to grow reference cultures for QC testing is included in this one handy device. The products are unassayed, meaning it is not intended to be used with any specific assay. 01245P contains Klebsiella pneumoniae derived from NCTC 13439
1.	5. Device Model/Catalogue/part number(s)*
	01245P
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	01245P Lot: 1245-03-1, 1245-03-2, 1245-03-3, 1245-03-4, 1245-04-1
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Strain is supposed to be VIM-1 positive. Strain was confirmed to be VIM-1 negative using the Nanosphere Verigene BC-GN assay, IP/IPI eTest for Metallo Beta-Lactamase and mCIM/eCIM testing.
2.	2. Hazard giving rise to the FSCA*

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	There is low health risk posed by this non-conformance. This product is used for Quality Control. When Quality Control does not pass, the patient isolate results cannot be reported. All testing would need to be repeated which could potentially lead to delayed test results for the patient and customer dissatisfaction. Patient treatment may be delayed depending on the facility. However, laboratory testing is not the only factor that would be considered when determining a patients' treatment plan. Physicians also relay on the patient's symptom and other test results. This scenario has been evaluated in the Risk Assessment for the KWIK-STIK™ and LYFO DISK™ products. However, if the patient does have a Carbapenem resistant Klebsiella pneumoniae infection, a delayed diagnosis and consequent ineffective treatment may adversely affect the patient's outcome. Carbapenem resistant infections are very rare, but infections from these "super bugs" do occur, and are more likely to occur in a healthcare/hospital setting.
2.	3. Probability of problem arising
	This product is used as a Quality Control. If the user is testing for Metallo Beta-Lactamase activity or performing molecular testing for the presence of the gene the results will be negative. If this product is not used specifically for VIM-1/Metallo Beta-Lactamase there will be no impact on the results.
2.	4. Predicted risk to patient/users
	Investigation showed the gene is not present in product made from the 1245-03 and 1245-04 Bulk. This means that all customers using this product to test for VIM-1/Metallo Beta-Lactamase will get negative results instead of positive and will be unable to validate their instruments for this resistance mechanism/gene or if they are using it as a QC they will not be able to release results until they confirm the instrument can detect this by alternate means. If customers are only using the product for detection of Klebsiella pneumoniae they will not be impacted. If the patient does have a Carbapenem resistant Klebsiella pneumoniae infection, a delayed diagnosis and consequent ineffective antibiotic treatment has the potential to adversely affect the patient's outcome. The ineffective treatment with Carbapenems may cause the infection to worsen until treatment is replaced by another novel antibiotic.
2.	5. Further information to help characterize the problem
	N/A
2.	6. Background on Issue
	N/A
2.	7. Other information relevant to FSCA
	N/A

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	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 Use or discard the affected products depending on your lab procedures and how this information affects your usage of the product.	
3.	2. By when should the action be completed?	Upon receipt of this notice
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No	
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 Quarantine all current stock and initiate FSCA	
3	6. By when should the action be completed?	completed
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	

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	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	Microbiologics, Inc.
	b. Address	200 Cooper Ave North, St. Cloud, MN 56303 USA
	c. Website address	www.microbiologics.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Customer Reply Form
4.	10. Name/Signature	Shannon Hodel-Hanson, Technical Support Specialist
		Shannon Hodel-Hanson

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organizations 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.*

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