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

FSN Ref: 2020003 FSCA Ref: N/A

Date: 24/09/2020

Urgent Field Safety Notice
Device Commercial Name

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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Urgent Field Safety Notice (FSN)

0947P KWIK-STIK™ 2 Pack Streptococcus pneumoniae derived from ATCC® 49619
0947K KWIK-STIK™ 6 Pack Streptococcus pneumoniae derived from ATCC® 49619
0947L LYFO DISK™ Streptococcus pneumoniae derived from ATCC® 49619

5193P Qc Sets and Panel GP Comprehensive QC Set

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)
	0947P KWIK-STIK™ 2 Pack Streptococcus pneumoniae derived from ATCC® 49619™ 0947K KWIK-STIK™ 6 Pack Streptococcus pneumoniae derived from ATCC® 49619™ 0947L LYFO DISK™ Streptococcus pneumoniae derived from ATCC® 49619™ 5193P QC Sets and Panels GP Comprehensive QC Set
1.	3. Unique Device Identifier(s) (UDI-DI)
	0947P UDI: 20845357022947 0947K UDI: 30845357022951 0947L UDI: 10845357022964 5193P UDI: 70845357030718
1.	4. Primary clinical purpose of device(s)*
	KWIK-STIK™ and LYFO-DISK™ 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. Each LYFO-DISK™ contains 6 lyophilized pellets for flexibility in the lab. The products are unassayed, meaning it is not intended to be used with any specific assay. 0947P, 0947K, 0947L contain Streptococcus pneumoniae derived from ATCC®49619™ 5193P GP Comprehensive QC Panel contains two KWIK-STIKs of each strain listed below (18 KWIK-STIKs total). This set contains 0947P as one component: 0761P Enterococcus casseliflavus derived from ATCC® 700327™* 0223P Enterococcus saccharolyticus derived from ATCC® 43076™* 0126P Kocuria kristinae derived from ATCC® BAA-752™* 0130P Listeria monocytogenes derived from ATCC® BAA-751™* 0134P Staphylococcus saprophyticus derived from ATCC® BAA-750™* 0764P Staphylococcus sciuri subsp. sciuri derived from ATCC® 29061™* 0101P Streptococcus equi subsp. zooepidemicus derived from ATCC® 43079™* **0947P Streptococcus pneumoniae derived from ATCC® 49619™*** 0136P Streptococcus salivarius subsp. thermophilus derived from ATCC® 19258™*

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1.	5. Device Model/Catalogue/part number(s)*
	0947P, 0947K, 0947L, and 5193P
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	0947P Lot: 947-126-2, 947-126-4 0947K Lot: 947-126-3 0947L Lot : 947-126-1 5193P Lot: 5193-10 and 5193-11
1.	8. Associated devices
	N/A

	2. **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	Low level contamination with S.epidermidis and E.coli
2.	2. Hazard giving rise to the FSCA*
	These products are controls for diagnostic assays (but they are not diagnostics themselves). There is no health risk posed by this non-conformance. This product is used to QC the Vitek 2 GP Identification cards and only an isolated colony should be used. Quality Control would not pass if the wrong colony type was used. Testing would have to be repeated and 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.
2.	3. Probability of problem arising
	Investigation results show that the OOS result is not repeated 100%. Some users may use the lot and never experience a susceptible result, while some may. Probability of a user being impacted is very low, and more of an inconvenience and not a safety issue.
2.	4. Predicted risk to patient/users
	These products are controls for diagnostic assays (but they are not diagnostics themselves). There is no health risk posed by this non-conformance. This product is used to QC the Vitek 2 GP Identification cards and only an isolated colony should be used. Quality Control would not pass if the wrong colony type was used. Testing would have to be repeated and 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.
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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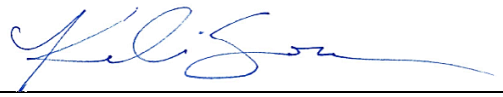
	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further 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. * After a risk assessment, national competent authorities have not been notified about this communication because there is no risk of harm to patients or users.	
4.	9. List of attachments/appendices:	Customer Reply Form
4.	10. Name/Signature	Kali Sorum, Technical Support Manager
		

	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.*

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

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Field Safety Notice
Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2020003
FSN Date*	24/09/2020
Product/ Device name*	0947P KWIK-STIK™ 2 Pack Streptococcus pneumoniae derived from ATCC® 49619™ 0947K KWIK-STIK™ 6 Pack Streptococcus pneumoniae derived from ATCC® 49619™ 0947L LYFO DISK™ Streptococcus pneumoniae derived from ATCC® 49619™ 5193P QC Sets and Panels GP Comprehensive QC Set
Product Code(s)	0947P, 0947K, 0947L 5193P
Batch/Serial Number (s)	Catalog Number 0947P Lot: 947-126-2, 947-126-4 Catalog Number 0947K Lot: 947-126-3 Catalog Number 0947L Lot : 947-126-1 Catalog Number 5193P Lot: 5193-10 and 5193-11

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	ksorum@microbiologics.com
Distributor/Importer Helpline	+1-320-229-7045
Postal Address	200 Cooper Avenue North Saint Cloud, MN 56303, USA
Web Portal	www.microbiologics.com
Deadline for returning the Distributor/Importer reply form*	01/11/2020

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date

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☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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Field Safety Notice
Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2020003
FSN Date*	24/09/2020
Product/ Device name*	0947P KWIK-STIK™ 2 Pack Streptococcus pneumoniae derived from ATCC® 49619™ 0947K KWIK-STIK™ 6 Pack Streptococcus pneumoniae derived from ATCC® 49619™ 0947L LYFO DISK™ Streptococcus pneumoniae derived from ATCC® 49619™ 5193P QC Sets and Panels GP Comprehensive QC Set
Product Code(s)	0947P, 0947K, 0947L 5193P
Batch/Serial Number (s)	Catalog Number 0947P Lot: 947-126-2, 947-126-4 Catalog Number 0947K Lot: 947-126-3 Catalog Number 0947L Lot : 947-126-1 Catalog Number 5193P Lot: 5193-10 and 5193-11

2. Customer Details	
Account Number	
Healthcare Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):

	complete.	N/A	Comments:
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
☐	No affected devices are available for return/	Customer to complete or enter N/A	

	destruction	
☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	01/11/2020

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.