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FSN Ref: 2020004 FSCA Ref: N/A

Date: 05/10/2020

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)

0318P KWIK-STIK™ 2 Pack Clostridium perfringens derived from ATCC® 13124™

5190P QC Sets and Panel ANC 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)
	0318P KWIK-STIK™ 2 Pack Clostridium perfringens derived from ATCC® 13124™ 5190P QC Sets and Panel ANC Comprehensive QC Set
1.	3. Unique Device Identifier(s) (UDI-DI)
	0318P UDI: 20845357006213 5190P UDI: 70845357030626
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. 0318P KWIK-STIK™ 2 Pack Clostridium perfringens derived from ATCC® 13124™ 5190P QC Sets and Panel ANC Comprehensive QC Set contains two KWIK-STIKs of each strain listed below (14 KWIK-STIKs total). This set contains 0318P as one component: 0585P Bacteroides ovatus derived from ATCC® BAA-1296™ 0445P Bacteroides vulgatus derived from ATCC® 8482™ 0318P Clostridium perfringens derived from ATCC® 13124™ 0586P Clostridium septicum derived from ATCC® 12464™ 0331P Paeniclostridium sordellii derived from ATCC® 9714™ 0583P Corynebacterium striatum derived from ATCC® BAA-1293™ 0584P Parabacteroides distasonis derived from ATCC® BAA-1295™
1.	5. Device Model/Catalogue/part number(s)*
	0318P, 5190P
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range

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	0318P Lot: 318-234-4 5190P Lot: 5190-08
1.	8. Associated devices
	N/A

	2. Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Mislabeled foil pouch that the individual KWIK-STIK™ is placed in; the foil pouch is labeled as lot 218-234-4. All other labels (KWIK-STIK™ device, KWIK-STIK™ canister, and Certificate of Analysis are correct.
2.	2. Hazard giving rise to the FSCA*
	All foil pouches for lot 318-234-4 have the lot number misprinted as 218-234-4. The canister label is correct, and the label on the actual KWIK-STIK is correct. The KWIK-STIK label is detached by the user and used to identify the plate. If the end-user stores the KWIK-STIKs in the canister and opens the pouch without noticing the pouch label is incorrect, the user would not be affected.
2.	3. Probability of problem arising
	All customers that have received this lot may experience this hazard.
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. Since the KWIK-STIK™ device label and KWIK-STIK™ canister labels are correct, the end-user may not noticed the mislabeled foil pouch. If the end-user stores the KWIK-STIK™ outside of the canister, they may notice the misprinted lot number on the foil pouch, but the KWIK-STIK™ device label will be correct on the inside. The KWIK-STIK™ device label is what customers tear off to label their agar plate with.
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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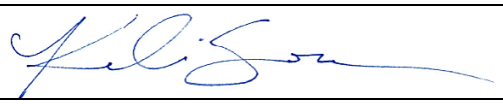
	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further 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*	2020004
FSN Date*	05/10/2020
Product/ Device name*	0318P KWIK-STIK™ 2 Pack Clostridium perfringens derived from ATCC® 13124™
Product Code(s)	0318P
Batch/Serial Number (s)	Catalog Number 0318P Lot: 318-234-4

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	claudenbach@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*	01/12/2020

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
☐	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

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☐	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*	2020004
FSN Date*	05/10/2020
Product/ Device name*	0318P KWIK-STIK™ 2 Pack *Clostridium perfringens* derived from ATCC® 13124™
Product Code(s)	0318P
Batch/Serial Number (s)	Catalog Number 0318P Lot: 318-234-4

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 complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		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*	01/12/2020

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.