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

FSN Ref: 20210001 FSCA Ref: N/A

Date: xx/2/2021

Urgent Field Safety Notice

Catalog 0726P Candida parapsilosis derived from ATCC® 22019™

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)

Catalog 0726P Candida parapsilosis derived from ATCC® 22019™

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)
	Catalog 0726P Candida parapsilosis derived from ATCC® 22019™
1.	3. Unique Device Identifier(s) (UDI-DI)
	0726P UDI: 20845357017486
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.
1.	5. Device Model/Catalogue/part number(s)*
	0726P
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	726-57-10
1.	8. Associated devices
	N/A

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	2. **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*	
	A small number of products packaged for lot 726-57-10 were packaged in foil pouches labeled as 323-108-7.	
2.	2. Hazard giving rise to the FSCA*	
	A complaint investigation showed that a small number of products packaged for lot 726-57-10 were packaged in pouches labeled as 323-108-7, which is a labeling violation.	
2.	3. Probability of problem arising	
	A limited number of KWIK-STIKs for lot 726-57-10 were packaged in pouches labeled as 323-108-7. Some customers that have received this lot may experience this hazard. The canister label and the label on the actual KWIK-STIK are 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.	4. Predicted risk to patient/users	
	There is negligible health risk posed by this non-conformance. This product is used as a Quality Control. Some customers that have received this lot may experience this hazard. 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. 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. *	
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.