



FSN Ref: 2025006

FSCA Ref: N/A

Date: 18 FEB 2026

Urgent Field Safety Notice (FSN)

**Campylobacter jejuni subsp. jejuni derived from ATCC® 29428™
Catalog Numbers 0325P, 0325K, and 0325L**

For Attention of*: Clinical Laboratory managers and lab technicians.

Contact details of local representative (name, e-mail, telephone, address etc.)*

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**Campylobacter jejuni subsp. jejuni derived from ATCC® 29428™
 Catalog Numbers 0325P, 0325K, and 0325L**

Risk addressed by FSN

1. Information on Affected Devices*	
1.	<p>1. Device Type(s)* Unassayed quality control material for microbiology assays.</p>
1.	<p>2. Commercial name(s) KWIK-STIK™ 2-Pack Campylobacter jejuni subsp. jejuni derived from ATCC® 29428™ KWIK-STIK™ 6-Pack Campylobacter jejuni subsp. jejuni derived from ATCC® 29428™ LYFO DISK™ Campylobacter jejuni subsp. jejuni derived from ATCC® 29428™</p>
1.	<p>3. Unique Device Identifier(s) (UDI-DI) 0325P: 20845357006459 0325K: 30845357006463 0325L: 10845357006476</p>
1.	<p>4. Primary clinical purpose of device(s)* KWIK-STIK™ and LYFO DISK™ are intended to be external clinically-relevant viable control materials (as specified in Annex 1† by catalog number) to assist in identification of cultured microorganism isolates, and to verify the performance of assays, reagents, or media that are intended to be used in microbial testing. These products have no qualitative or quantitative assigned value. These control materials are nonautomated and not intended to be used for screening, monitoring, or diagnosis. These controls are not intended for any specific patient population or specimen. †Annex 1 lists all catalog numbers in the KWIK-STIK and LYFO DISK product families, which includes 0325P, 0325K, and 0325L.</p>
1.	<p>5. Device Model/Catalogue/part number(s)* 0325P, 0325K, and 0325L</p>
1.	<p>6. Software version N/A</p>
1.	<p>7. Affected serial or lot number range 325-120-1, 325-120-3, 325-120-4, 325-120-5, 325-120-6, 325-120-7 325-119-1, 325-119-2, 325-119-3, 325-119-5, 325-119-6</p>
1.	<p>8. Associated devices N/A</p>

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem* Microbiologics KWIK-STIK™ and LYFO DISK™ products containing Campylobacter jejuni subsp. jejuni derived from ATCC® 29428™ did not show any recovery despite following all recommended procedures.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p>

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	There have been no reports of disease or injury from the use of the device. There is no specific patient population at risk. 0325P, 0325K, and 0325L are class B (IVDR) quality control materials; they are not diagnostic devices. The main risk to the patient is delayed diagnosis. Generally, physicians do not rely solely on lab tests before deciding on treatment. Patient symptoms are reviewed, and multiple tests may be conducted. If a physician were relying solely on this control material, patient results and treatment may be delayed.
2.	3. Probability of problem arising From health hazard evaluation – Probability = 1 (improbable) likely to never happen ($p \leq 10^{-5}$).
2.	4. Predicted risk to patient/users From health hazard evaluation – Severity = 1 (negligible). Risk factor scoring $1 \times 1 = 1$ (low).
2.	5. Further information to help characterize the problem N/A
2.	6. Background on Issue No additional information available.
2.	7. Other information relevant to FSCA N/A



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3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input checked="" type="checkbox"/> Other – use as-is <input type="checkbox"/> None </p>
3.	<p>2. By when should the action be completed? Upon receipt of this notice</p>
3.	<p>3. Particular considerations for: N/A</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p>
3.	<p>4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) No</p>
3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Revise FSN and send to all affected distributors</p>
3	<p>6. By when should the action be completed? Completed</p>
3.	<p>7. Is the FSN required to be communicated to the patient /lay user? No</p>
3.	<p>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</p>



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4. General Information*	
4.	1. FSN Type* Update
4.	2. For updated FSN, reference number and date of previous FSN FSN 2025006 dated 29 DEC 2025
4.	3. For Updated FSN, key new information as follows: Further investigation and testing have demonstrated the observed lack of growth was attributable to one specific chocolate agar media formulation and not to the lyophilized control material itself. The control material performs as intended when cultured on validated media as described in the instructions for use. Customers may continue to use the affected lots of the control materials identified in this FSN. No product return or destruction is required.
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: N/A
4.	10. Name/Signature Brian Carter Senior Regulatory Specialist

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organizations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

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

Field Safety Notice Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2025006
FSN Date*	18 FEB 2026
Product/ Device name*	KWIK-STIK™ 2-Pack Campylobacter jejuni subsp. jejuni derived from ATCC® 29428™ KWIK-STIK™ 6-Pack Campylobacter jejuni subsp. jejuni derived from ATCC® 29428™ LYFO DISK™ Campylobacter jejuni subsp. jejuni derived from ATCC® 29428™
Product Code(s)	0325P, 0325K, 0325L
Batch/Serial Number (s)	0325P : 325-120-3; 325-120-7; 325-119-1; 325-119-5; 0325K : 325-120-1; 325-120-4; 325-120-6; 325-119-2; 0325L : 325-120-5; 325-119-3; 325-119-6

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

3. Return acknowledgement to Sender (pre-filled by manufacturer/sender/requester)	
Email	recall@microbiologics.com
Distributor/Importer Helpline	+1 320.229.7080
Postal Address	200 Cooper Avenue North, St. Cloud, MN 56303, USA
Web Portal	N/A
Deadline for returning the Distributor/Importer reply form*	31 MAR 2026

4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication



<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	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)
<input type="checkbox"/>	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)
<input type="checkbox"/>	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 *		Distributor/Importer date here

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.

