

FSN Ref: 2025004

FSCA Ref: N/A

Date: 24 JUN 2025

Urgent Field Safety Notice (FSN)

**Brevundimonas diminuta derived from ATCC® 19146™
Catalog Numbers 0805K and 0805L**

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

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



Urgent Field Safety Notice (FSN)**Brevundimonas diminuta derived from ATCC® 19146™
Catalog Numbers 0805K and 0805L****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) KWIK-STIK™ 6-Pack 0805K Brevundimonas diminuta derived from ATCC® 19146™ LYFO DISK™ 0805L Brevundimonas diminuta derived from ATCC® 19146™
1.	3. Unique Device Identifier(s) (UDI-DI) 0805K: 30845357019531 0805L: 10845357019544
1.	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 0805K and 0805L.
1.	5. Device Model/Catalogue/part number(s)* 0805K and 0805L
1.	6. Software version N/A
1.	7. Affected serial or lot number range 805-234-4 and 805-234-5
1.	8. Associated devices N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* The wrong lyophilized pellet was packaged. KWIK-STIK™ catalog number 0805K and LYFO-DISK™ catalog number 0805L are expected to contain Brevundimonas diminuta. However, lot numbers 805-234-4 and 805-234-5 actually contain Staphylococcus epidermidis.
2.	2. Hazard giving rise to the FSCA* There have been no reports of disease or injury from the use of the device. There is no specific patient population at risk. 0805K and 0805L 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.


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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 = 3 (serious). Risk factor scoring $1 \times 3 = 3$ (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



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 checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" 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 type="checkbox"/> Other <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) Yes</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>Quarantine all affected stock and initiate FSCA.</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>

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: FSN Customer Reply Form
4.	10. Name/Signature 

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.