Microbiologics®
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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.)*

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| 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™<br>0947K KWIK-STIK™ 6 Pack Streptococcus pneumoniae derived from ATCC® 49619™<br>0947L LYFO DISK™ Streptococcus pneumoniae derived from ATCC® 49619™<br><br>5193P QC Sets and Panels GP Comprehensive QC Set |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 0947P UDI: 20845357022947<br>0947K UDI: 30845357022951<br>0947L UDI: 10845357022964<br><br>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.<br><br>0947P, 0947K, 0947L contain Streptococcus pneumoniae derived from ATCC®49619™<br><br>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:<br><br>0761P Enterococcus casseliflavus derived from ATCC® 700327™*<br>0223P Enterococcus saccharolyticus derived from ATCC® 43076™*<br>0126P Kocuria kristinae derived from ATCC® BAA-752™*<br>0130P Listeria monocytogenes derived from ATCC® BAA-751™*<br>0134P Staphylococcus saprophyticus derived from ATCC® BAA-750™*<br>0764P Staphylococcus sciuri subsp. sciuri derived from ATCC® 29061™*<br>0101P Streptococcus equi subsp. zooepidemicus derived from ATCC® 43079™*<br>**0947P Streptococcus pneumoniae derived from ATCC® 49619™***<br>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<br>0947K Lot: 947-126-3<br>0947L Lot : 947-126-1<br><br>5193P Lot: 5193-10 and 5193-11 |
| 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* |
| | 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*** <br> ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device <br> ☐ On-site device modification/inspection <br> ☐ Follow patient management recommendations <br> ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) <br> ☒ Other ☐ None <br> 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 <br> Is follow-up of patients or review of patients' previous results recommended? <br> No | |
| 3. | 4. Is customer Reply Required? * <br> (If yes, form attached specifying deadline for return) | Yes |
| 3. | **5. Action Being Taken by the Manufacturer** <br> ☐ Product Removal ☐ On-site device modification/inspection <br> ☐ Software upgrade ☐ IFU or labelling change <br> ☒ Other ☐ None <br> 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? <br> N/A | |

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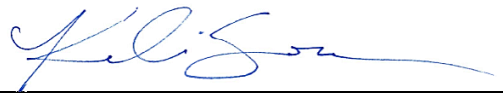
| | **4. General Information*** | |
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | N/A |
| 4. | 3. For Updated FSN, key new information as follows: | |
| | N/A | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | No |
| 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 |
| | |  |

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