

FSN Ref: 2020001

FSCA Ref: N/A

Date: 17/02/2020

Urgent Field Safety Notice

**Microbiologics 0778P KWIK-STIK™ Trichosporon dermatis ATCC 204094™
Microbiologics 5195P QC Sets and Panels: KWIK-STIK™ YST Comprehensive QC Set**

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)

Microbiologics 0778P KWIK-STIK™ Trichosporon dermatis ATCC 204094™
Microbiologics 5195P QC Sets and Panels: KWIK-STIK™ YST Comprehensive QC Set

Risk addressed by FSN

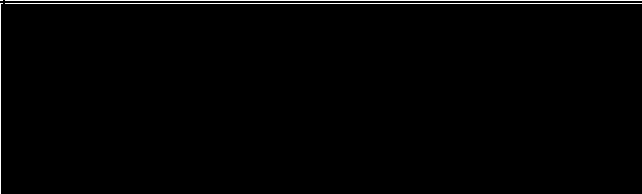
| 1. Information on Affected Devices* | |
|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | <p>1. Device Type(s)*</p> <p>Unassayed quality control material for microbiology assays.</p> |
| 1. | <p>2. Commercial name(s)</p> <p>0778P KWIK-STIK™ Trichosporon dermatis ATCC 204094™ 5195P QC Sets and Panels: KWIK-STIK™ YST Comprehensive QC Set</p> |
| 1. | <p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>0778P: 20845357018773 5195P: 70845357030770</p> |
| 1. | <p>4. Primary clinical purpose of device(s)*</p> <p>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. 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. The product is unassayed, meaning it is not intended to be used with any specific assay.</p> <p>0778P contains Trichosporon dermatis derived from ATCC® 204094™.</p> <p>5195P YST Comprehensive QC Set contains two KWIK-STIKs of each strain listed below (22 KWIK-STIKs total). This set contains 0778P as one component.</p> <p>0332P Candida albicans derived from ATCC® 14053™ 0122P Candida glabrata derived from ATCC® MYA-2950™ 0774P Candida lusitanae derived from ATCC® 34449™ 0779P Candida utilis derived from ATCC® 9950™ 01012P Hanseniaspora valbyensis derived from ATCC® 58370™ 0868P Oligella ureolytica derived from ATCC® 43534™ 0780P Prototheca wickerhamii derived from ATCC® 16529™ 0371P Staphylococcus epidermidis derived from ATCC® 12228™ 01013P Sporidiobolus salmonicolor derived from ATCC® MYA-4550™ 0778P Trichosporon dermatis derived from ATCC® 204094™ 01011P Zygosaccharomyces parabailii derived from ATCC® MYA-4549™</p> |
| 1. | <p>5. Device Model/Catalogue/part number(s)*</p> <p>0778P and 5195P</p> |
| 1. | <p>6. Software version</p> <p>N/A</p> |
| 1. | <p>7. Affected serial or lot number range</p> <p>778-65-3, 5195-04, and 5195-05</p> |
| 1. | <p>8. Associated devices</p> <p>N/A</p> |

| 2. Reason for Field Safety Corrective Action (FSCA)* | |
|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2. | 1. Description of the product problem* A limited portion of lot number 778-65-3 contains an organism that is different than presented by its labeling. It should contain Trichosporon dermatis but instead contains Candida utilis. A limited portion of the product is mislabeled. This is the only lot number affected and only 2-packs are affected (no 6-packs). |
| 2. | 2. Hazard giving rise to the FSCA* This labeling error may cause a user's quality control to fail, resulting in testing needing to be repeated. |
| 2. | 3. Probability of problem arising Based on our root cause analysis, we estimate a small probability of other users being affected. The majority of the lot was completed correctly, and at the end of the lot, there were not enough KWIK-STIKs assigned to the lot. Consequently, a small number of KWIK-STIKs were obtained to complete the order quantity, and the wrong bulk pellets were chosen to build the KWIK-STIKs. We expect no more than 5 additional customers to be affected, which is approximately 10% of remaining customers. The customer will know with 100% certainty if they receive the wrong microorganism, because the QC test will fail unexpectedly. |
| 2. | 4. Predicted risk to patient/users This product is a control material used in clinical labs to test media, reagents and methods. This labeling error may cause a user's quality control to fail, resulting in testing needing to be repeated. This may result in delayed test results and an inconvenience for the test lab. There is no affect to patients. The organisms involved are not the same biosafety level but this does not pose an additional risk to laboratory as safety precautions in BSL1 & 2 labs are similar. Also, the actual microorganism received is BSL1, while the correct organism ordered is BSL2, so they received a lower risk microorganism than expected. |
| 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 |

| 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 checked="" type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p> | | |
| 3. | <table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">2. By when should the action be completed?</td> <td>Upon receipt of this notice.</td> </tr> </table> | 2. By when should the action be completed? | Upon receipt of this notice. |
| 2. By when should the action be completed? | Upon receipt of this notice. | | |
| 3. | <p>3. Particular considerations for:</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p> | | |
| 3. | <table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td style="text-align: center;">Yes</td> </tr> </table> | 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) | Yes |
| 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) | Yes | | |
| 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 current stock and initiate FSCA</p> | | |
| 3 | <table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">6. By when should the action be completed?</td> <td>Completed</td> </tr> </table> | 6. By when should the action be completed? | Completed |
| 6. By when should the action be completed? | Completed | | |
| 3. | <table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">7. Is the FSN required to be communicated to the patient /lay user?</td> <td style="text-align: center;">No</td> </tr> </table> | 7. Is the FSN required to be communicated to the patient /lay user? | No |
| 7. Is the FSN required to be communicated to the patient /lay user? | No | | |
| 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?</p> <p>N/A</p> | | |

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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 Avenue 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  |

| 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 Customer Reply Form

| 1. Field Safety Notice (FSN) information | |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| FSN Reference number* | 2020001 |
| FSN Date* | 17/02/2020 |
| Product/ Device name* | Microbiologics 0778P KWIK-STIK™ Trichosporon dermatis ATCC 204094™ Microbiologics 5195P QC Sets and Panels: KWIK-STIK™ YST Comprehensive QC Set |
| Product Code(s) | 0778P, 5195P |
| Batch/Serial Number (s) | 778-65-3, 5195-04, and 5195-05 |

| 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 | | | |
|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-----------------------------------|---------------------------------------------------|
| <input type="checkbox"/> | I confirm receipt of the Field Safety Notice and that I read and understood its content. | Customer to complete or enter N/A | |
| <input type="checkbox"/> | I performed all actions requested by the FSN. | Customer to complete or enter N/A | |
| <input type="checkbox"/> | The information and required actions have been brought to the attention of all relevant users and executed. | Customer to complete or enter N/A | |
| <input type="checkbox"/> | 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: |
| <input type="checkbox"/> | I have destroyed affected devices – enter number destroyed and date complete. | Qty: | Lot/Serial Number: |
| | | Qty | Lot/Serial Number: |
| | | N/A | Comments: |
| <input type="checkbox"/> | No affected devices are available for return/ | Customer to complete or enter N/A | |

| | | |
|--------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| | destruction | |
| <input type="checkbox"/> | Other Action (Define): | |
| <input type="checkbox"/> | I do not have any affected devices. | Customer to complete or enter N/A |
| <input type="checkbox"/> | 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* | 31/03/2020 |

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.