

Rev 1: September 2018

FSN Ref: FSN-2024-005

FSCA Ref: FSN-2024-005

Date: 20 November 2024

**Urgent Field Safety Notice**  
**Thermo Scientific™ Yersinia Selective Agar**  
**PO5044A Lot 6190052 Exp. 27-December-2024**

For Attention of\*: Lab Managers

|                                                                                  |
|----------------------------------------------------------------------------------|
| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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|                                                                                             |
|---------------------------------------------------------------------------------------------|
| E.mail : <a href="mailto:mbd.vigilance@thermofisher.com">mbd.vigilance@thermofisher.com</a> |
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| Telephone: +44(0) 1256 841144 |
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| Fax: +44(0) 1256 479525 |
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**Urgent Field Safety Notice (FSN)**  
**Thermo Scientific™ Yersinia Selective Agar**  
**PO5044A Lot 6190052 Exp. 27-December-2024**

| 1. Information on Affected Devices* |                                                                                                                        |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| 1.                                  | 1. Device Type(s)*                                                                                                     |
|                                     | Prepared Plate Media (IVD)                                                                                             |
| 1.                                  | 2. Commercial name(s)                                                                                                  |
|                                     | Thermo Scientific™ Yersinia Selective Agar                                                                             |
| 1.                                  | 3. Unique Device Identifier(s) (UDI-DI)                                                                                |
|                                     | 5032384129140                                                                                                          |
| 1.                                  | 4. Primary clinical purpose of device(s)*                                                                              |
|                                     | A selective medium for the isolation of <i>Yersinia enterocolitica</i> .<br>Can also be used for testing food samples. |
| 1.                                  | 5. Device Model/Catalogue/part number(s)*                                                                              |
|                                     | PO5044A                                                                                                                |
| 1.                                  | 6. Software version                                                                                                    |
|                                     | N/A                                                                                                                    |
| 1.                                  | 7. Affected serial or lot number range                                                                                 |
|                                     | 6190052                                                                                                                |
| 1.                                  | 8. Associated devices                                                                                                  |
|                                     | N/A                                                                                                                    |

| 2. Reason for Field Safety Corrective Action (FSCA)* |                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.                                                   | 1. Description of the product problem*                                                                                                                                                                                                                                                                                                                                                                                                  |
|                                                      | An internal investigation has identified that <i>Pseudomonas aeruginosa</i> may not be inhibited on this batch of agar. Additional lots have been tested and found to be performing as intended.                                                                                                                                                                                                                                        |
| 2.                                                   | 2. Hazard giving rise to the FSCA*                                                                                                                                                                                                                                                                                                                                                                                                      |
|                                                      | Continued use of this lot may result in delay to patient treatment.                                                                                                                                                                                                                                                                                                                                                                     |
| 2.                                                   | 3. Probability of problem arising                                                                                                                                                                                                                                                                                                                                                                                                       |
|                                                      | High. The data collected demonstrates that the identified batch does not inhibit <i>Pseudomonas aeruginosa</i> .                                                                                                                                                                                                                                                                                                                        |
| 2.                                                   | 4. Predicted risk to patient/users                                                                                                                                                                                                                                                                                                                                                                                                      |
|                                                      | No serious adverse health consequences should be observed. Yersiniosis is primarily a gastrointestinal infection that occurs in persons who have ingested shellfish or who have been exposed from brackish waters.<br>Cefsulodin is present to prevent growth of <i>P. aeruginosa</i> , which is very uncommon in these types of faecal samples.<br>It is not likely, that the use of the affected batch will cause any adverse events. |
| 2.                                                   | 5. Further information to help characterise the problem                                                                                                                                                                                                                                                                                                                                                                                 |
|                                                      | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.                                                   | 6. Background on Issue                                                                                                                                                                                                                                                                                                                                                                                                                  |
|                                                      | The root cause of this issue is yet to be determined.                                                                                                                                                                                                                                                                                                                                                                                   |
| 2.                                                   | 7. Other information relevant to FSCA                                                                                                                                                                                                                                                                                                                                                                                                   |
|                                                      | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                     |

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| 3. Type of Action to mitigate the Risk* |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| 3.                                      | <b>1. Action To Be Taken by the User*</b><br><br><input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device<br><br><input type="checkbox"/> On-site device modification/inspection<br><br><input checked="" type="checkbox"/> Follow patient management recommendations<br><br><input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)<br><br><input type="checkbox"/> Other <input type="checkbox"/> None |                     |
| 3.                                      | 2. By when should the action be completed?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Without undue delay |
| 3.                                      | <b>3. Particular considerations for: IVD</b><br><br>Is follow-up of patients or review of patients' previous results recommended?<br>Yes<br><br>Clinical tests should be reviewed and retested as required.                                                                                                                                                                                                                                                                                                                                                                             |                     |
| 3.                                      | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                 |
| 3.                                      | <b>5. Action Being Taken by the Manufacturer</b><br><br><input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection<br><input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change<br><input type="checkbox"/> Other <input type="checkbox"/> None                                                                                                                                                                                                                                               |                     |
| 3                                       | 6. By when should the action be completed?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Without undue delay |
| 3.                                      | 7. Is the FSN required to be communicated to the patient /lay user?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | No                  |
| 3                                       | <b>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?</b><br>Choose an item.            Choose an item. 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<br>(For contact details of local representative refer to page 1 of this FSN)           |                                                                  |
|                         | a. Company Name                                                                                                    | Oxoid Deutschland GmbH                                           |
|                         | b. Address                                                                                                         | Am Lippeglacis 4-8<br>46483, Wesel<br>Germany                    |
|                         | c. Website address                                                                                                 | www.thermofisher.com/microbiology                                |
| 4.                      | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * |                                                                  |
| 4.                      | 9. List of attachments/appendices:                                                                                 | Customer Response Form                                           |
| 4.                      | 10. Name                                                                                                           | Mr Paul Sherlock<br>Vice President, Quality & Regulatory,<br>MBD |
|                         | Signature                                                                                                          |                                                                  |

#### Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations 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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### Customer Reply Form

|                                                                           |                                                                                                             |                                                                                    |                                                                      |                           |
|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|----------------------------------------------------------------------|---------------------------|
| <b>1. Field Safety Notice (FSN) information</b>                           |                                                                                                             |                                                                                    |                                                                      |                           |
| FSN Reference number*                                                     |                                                                                                             | 2024-005                                                                           |                                                                      |                           |
| FSN Date*                                                                 |                                                                                                             | 20 November 2024                                                                   |                                                                      |                           |
| Product/ Device name*                                                     |                                                                                                             | Thermo Scientific™ Yersinia Selective Agar                                         |                                                                      |                           |
| Product Code(s)                                                           |                                                                                                             | PO5044A                                                                            |                                                                      |                           |
| Batch/Serial Number (s)                                                   |                                                                                                             | 6190052                                                                            |                                                                      |                           |
| <b>2. Customer Details</b>                                                |                                                                                                             |                                                                                    |                                                                      |                           |
| Account Number                                                            |                                                                                                             |                                                                                    |                                                                      |                           |
| Organisation Name*                                                        |                                                                                                             |                                                                                    |                                                                      |                           |
| Organisation Address*                                                     |                                                                                                             |                                                                                    |                                                                      |                           |
| Department/Unit                                                           |                                                                                                             |                                                                                    |                                                                      |                           |
| Shipping address if different to above                                    |                                                                                                             |                                                                                    |                                                                      |                           |
| Contact Name*                                                             |                                                                                                             |                                                                                    |                                                                      |                           |
| Title or Function                                                         |                                                                                                             |                                                                                    |                                                                      |                           |
| Telephone number*                                                         |                                                                                                             |                                                                                    |                                                                      |                           |
| Email*                                                                    |                                                                                                             |                                                                                    |                                                                      |                           |
| <b>3. Customer action undertaken on behalf of Healthcare Organisation</b> |                                                                                                             |                                                                                    |                                                                      |                           |
| <input type="checkbox"/>                                                  | I confirm receipt of the Field Safety Notice and that I read and understood its content.                    |                                                                                    |                                                                      |                           |
| <input type="checkbox"/>                                                  | I performed all actions requested by the FSN.                                                               |                                                                                    |                                                                      |                           |
|                                                                           | The information and required actions have been brought to the attention of all relevant users and executed. |                                                                                    |                                                                      |                           |
| <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)  |
|                                                                           |                                                                                                             | Comments:                                                                          |                                                                      |                           |
| <input type="checkbox"/>                                                  | I have destroyed affected devices – enter number destroyed and date complete                                | Qty:                                                                               | Lot/Serial Number:                                                   | Date Completed (DD/MM/YY) |
|                                                                           |                                                                                                             | Qty                                                                                | Credit <input type="checkbox"/> Replacement <input type="checkbox"/> |                           |
|                                                                           |                                                                                                             | Comments:                                                                          |                                                                      |                           |
|                                                                           | No affected devices are available for return/ destruction                                                   |                                                                                    |                                                                      |                           |
|                                                                           | Other Action (Define):                                                                                      |                                                                                    |                                                                      |                           |
| <input type="checkbox"/>                                                  | I do not have any affected devices.                                                                         |                                                                                    |                                                                      |                           |
| <input type="checkbox"/>                                                  | I have a query please contact me (e.g. need for replacement of the product).                                |                                                                                    |                                                                      |                           |
| Print Name*                                                               |                                                                                                             |                                                                                    |                                                                      |                           |
| Signature*                                                                |                                                                                                             |                                                                                    |                                                                      |                           |
| Date*                                                                     |                                                                                                             |                                                                                    |                                                                      |                           |
| <b>4. Return acknowledgement to sender</b>                                |                                                                                                             |                                                                                    |                                                                      |                           |
| Email                                                                     |                                                                                                             | <a href="mailto:MBD.vigilance@thermofisher.com">MBD.vigilance@thermofisher.com</a> |                                                                      |                           |
| Telephone Number & Fax                                                    |                                                                                                             | Tel : +44(0) 1256 841144 & Fax :+44(0) 1256 479525                                 |                                                                      |                           |
| Postal Address                                                            |                                                                                                             |                                                                                    |                                                                      |                           |
| Deadline for returning the reply form*                                    |                                                                                                             | 18 December 2024                                                                   |                                                                      |                           |

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.**